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LEGISLATIVE AND REGULATORY RESPONSES TO THE FTC STUDY ON BARRIERS TO ENTRY IN THE PHARMACEUTICAL MARKETPLACE

HEARING

BEFORE THE

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LEGISLATIVE AND REGULATORY RESPONSES TO THE FTC STUDY ON BARRIERS TO ENTRY IN THE PHARMACEUTICAL MARKETPLACE

TUESDAY, JUNE 17, 2003

UNITED STATES SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Committee met, pursuant to notice, at 10:05 a.m., in room SD–226, Dirksen Senate Office Building, Hon. Orrin G. Hatch, Chairman of the Committee, presiding.

Present: Senators Hatch and Schumer.

OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM THE STATE OF UTAH

Chairman HATCH. Today, the Committee will hold a hearing in an area of great importance to the American public—competition in the pharmaceutical marketplace. This Congress has witnessed a growing spirit of bipartisan cooperation on pharmaceutical issues. After so many years of searching for consensus, we are all encouraged that the Finance Committee has now approved by a bipartisan majority the medicare reform and prescription drug benefit bill that we are now considering on the Senate floor.

President Bush deserves credit for encouraging the Congress to act in the best interests of the public on these matters. We owe a debt of gratitude, as well, to Senators Grassley and Baucus, Chairman and Ranking Member on the Finance Committee, for the work that they did over the last number of years which culminated last week in a passage of the bill out of committee.

I will give them my wholehearted support as the Senate debates the bill over the next two weeks. Having been a member of the so-called tripartisan group which developed and advanced the basic structure of this Medicare reform bill over a number of years, I am excited at the prospect of finally getting the job done for our seniors and those who are disabled in our society. But there is another set of issues relating to pharmaceuticals that promises to benefit the American public through increased competition in the pharmaceutical marketplace, and that is the subject of our hearing today.

This Committee held a hearing in May of 2001 on the issue of competition in the pharmaceutical marketplace. At that time, we discussed the anticompetitive behaviors made possible in part by the sometimes complex and admittedly confusing text of a law I co-

authored, the Drug Price Competition and Patent Term Restoration Act of 1984, sometimes called the Hatch-Waxman bill.

Since our last hearing on this issue, much has happened. Indeed, the HELP Committee has recently approved S. 1225, legislation which builds on that Committee's earlier McCain-Schumer initiative to address the cost of prescription drugs.

I must also single out both the Federal Trade Commission and the Food and Drug Administration for playing a constructive role in attempting to end several mechanisms by which some research-based and generic drug firms were attempting to game the system to avoid competition in the marketplace. Senator Leahy is to be commended, as well, for his legislative initiative, the Drug Competition Act, which I have cosponsored.

The agency has succeeded in winning several consent decrees with a variety of offending firms under the existing antitrust statutes. In addition, the FTC conducted an exhaustive survey and study of how certain provisions of the 1984 Waxman–Hatch Act affected competition in the pharmaceutical industry.

The FTC study contained two major recommendations, both of which we will examine today. The first addressed the use of the statutory 30-month stay granted by the 1984 law in situations where patents are challenged by generic competitors. The second responds to those situations in which R and D and generic firms were entering into agreements not to impede generic competition.

Our hearing will also examine how well the Bush administration's final rule effectuates a fair and thoughtful one, and only one, 30-month stay policy. Since the rule was finalized just last Thursday, none of us can understand all of its nuances. However, it does appear to be a good-faith attempt to implement the first FTC recommendation. But in an area this complex, no one should be surprised if we find that the agency inadvertently created new loopholes or unintentionally imposed unfair hardships that may need to be refined.

We will also examine today the patent provisions of the HELP Committee legislation, a bill I find much improved over last year's initiative, due in large part to the considerable influence of Chairman Gregg and, of course, Senator Schumer's work as well.

While I do have some concerns over this legislation which we will pursue in some detail this morning, I need to commend the sponsors of S. 1812 for moving in the right direction. I recognize that the language is something of a moving target, since there is under development a package of technical corrections that selected governmental and industry experts have commented upon. We will ask our witnesses today to comment on the legislation and the possible need for amendment.

It is unfortunate that the PTO was unable to present a witness today, albeit on short notice, and I will continue to press the agency for comments on how the bill and the final rule affect patent rights. It would have been preferable for the Committee to have the benefit of an agency official who could sit with his sister agencies and advise us on the patent provisions of S. 1225.

In closing, I have said many times that I prefer a comprehensive approach to Hatch-Waxman reform that includes a discussion of augmenting the existing intellectual property incentives and con-

sideration of whether and how to create a fast-track approval process for off-patent biologics. Nevertheless, I stand prepared, and the Judiciary Committee stands prepared to participate in any effort to revise the Drug Price Competition and Patent Term Restoration Act of 1984.

So I look forward to today's hearing, and we will look forward to our panels of witnesses and hope we can arrive at some good, effective work here today. On our first panel, we are pleased to have a number of witnesses from the administration.

First, we will hear from our friend, Tim Muris, Chairman of the Federal Trade Commission. The FTC allocates a significant share of its resources toward overseeing the health care sector, including the pharmaceutical industry. The July 2002 FTC study on generic drug entry prior to patent expiration is a key document for policymakers.

So we welcome you, Chairman Muris, and look forward to hearing your testimony here today.

Our second witness is Dan Troy, Chief Counsel for the Food and Drug Administration. The FDA just issued a final rule last Thursday that is intended, in part, to implement one of the major recommendations of the FTC report. Dan will help us to understand what the FDA rule does and how the rule would work with legislation under development that appears in large part an attempt to codify key elements of the FDA rule. It is my understanding that staff from both FTC and FDA have provided a considerable amount of so-called technical assistance toward the end of protecting the language that came out of the HELP Committee last week.

Our third witness on the panel, Sheldon Bradshaw, Deputy Assistant Attorney General, Office of Legal Counsel, will not submit prepared testimony. We are pleased that Mr. Bradshaw could appear here on relatively short notice.

Some have raised constitutional objections on the aspects of S. 1225, as reported. As the Department is still reviewing this issue and the language may be in flux, we do not expect Mr. Bradshaw to give any final administration views on this issue. He may be able to answer questions on what type of interagency review process may be underway to help answer this question and give us an idea when the Committee can expect a response.

Although I extended an invitation, absent from this panel is the representative from the Patent and Trademark Office. This is unfortunate but understandable, given that it may take some time for the experts at PTO to assess how the developments of last week, the FDA final rule, and the reporting of S. 1225 will affect patent law and policy. Even if we can't hear from them today, I expect them to present their views on these matters in a reasonable period of time.

Now, let's start with Chairman Muris. I would like you to summarize your remarks in seven minutes, if you can, and we will go from you to Dan Troy.

STATEMENT OF HON. TIMOTHY J. MURIS, CHAIRMAN, FEDERAL TRADE COMMISSION, WASHINGTON, D.C.

Mr. MURIS. Well, thank you very much, Mr. Chairman. I am not even sure I will take seven minutes, but let me just very briefly

address three points. First is the context of Hatch-Waxman, second is our enforcement agenda, and finally, briefly, a few evidentiary points from our study.

In terms of the Hatch-Waxman context, as I think we all know, advances in pharmaceuticals bring enormous benefits to Americans. Because of innovation, many medical conditions often can now be better treated with drug therapy than with alternative means such as surgery. We must maintain appropriate incentives for the development of such drugs.

In 1984, Congress enacted Hatch-Waxman. The amendment sought to balance incentives for continued innovation by research-based pharmaceutical companies, on the one hand, and opportunities for market entry by generic drugs on the other. Without question, Hatch-Waxman has increased generic entry. By purchasing generics, consumers have saved billions. Even greater savings are possible in the future.

Moving to the FTC's enforcement agenda, we have challenged conduct by firms allegedly gaming Hatch-Waxman to deter or delay generic competition. Our first generation of such matters involved agreements through which a brand name manufacturer allegedly paid a generic firm not to enter and compete, and to use the generic's rights under Hatch-Waxman to impede entry by others.

Our second generation of enforcement activities involves allegations that brand name manufacturers have delayed generic competition through a particular Hatch-Waxman provision that prohibits the FDA from approving a generic applicant for 30 months.

Brand name drug manufacturers sometimes act strategically to obtain more than one 30-month stay of FDA approval of a particular generic by listing patents in FDA's Orange Book after a generic company has submitted its application. The Commission recently obtained strong, and in some cases unprecedented relief against Bristol-Myers for this type of activity for its cancer drugs Taxol and Platinol, and its anti-anxiety drug BuSpar.

Finally, let me briefly discuss our study. It examined 104 brand name drugs between 1992 and 2000. We asked whether and how generic drug companies competed against brand name drug manufacturers before the patents expired.

Under Hatch-Waxman, brand name companies must list patents that claim each brand name drug in the Orange Book. A generic applicant then may certify that its product does not infringe the relevant patents or that those patents are invalid. If the brand name manufacturer sues the generic applicant for patent infringement, then the FDA may not approve the generic's application until a court determination of patent invalidity or non-infringement, or 30 months after receipt of the certification.

Our study found that 30 months has approximated the time necessary for FDA review and approval of a generic's application, as well as the time necessary for a district court to resolve the patent litigation. Nevertheless, for eight brand name drug products, the manufacturers have obtained more than one 30-month stay. This has caused considerable delay of FDA approval of the generic's application, ranging from 4 to 40 months of additional delay.

Our study recommends a limit of one automatic 30-month stay per drug product, per generic application, to resolve infringement

disputes over patents that were listed in the Orange Book prior to the filing of the generic's application. And we are certainly pleased that the FDA has adopted substantially that approach and that it is also in the new bill that you mentioned.

Our study also examined the Hatch-Waxman provision that awards 180 days of marketing exclusivity to the first generic to apply to enter the market before patent expiration. During this time, the FDA may not approve a subsequent generic. This provision provides an incentive for companies to challenge patent validity and to design around patents.

The data in our study found that generic applicants prevailed in about 75 percent of the patent litigation resolved by a court decision. Sometimes, however, the case is not litigated to a decision and there is a settlement. We found 14 settlement agreements that, when executed, had the potential to park the first generic applicant's 180-day exclusivity for some time, and thus prevent subsequent generic entry.

Because they can raise antitrust issues, the Commission supports the Drug Competition Act of 2001, introduced by Senator Leahy and passed by the Senate during the last Congress, that would require the filing of these types of agreements with the FTC and the Department of Justice.

Our study also made three minor recommendations to clarify the regulations governing the triggers for the 180-day marketing exclusivity. These recommendations should reduce any potential for the 180-day exclusivity provision to be a bottleneck to subsequent generic entry.

The Commission will continue to protect consumers from anticompetitive practices that inflate drug prices. We will continue to work closely with the Committee. I want to thank you, Mr. Chairman, on behalf of the Commission for your support of our work. I welcome your questions.

[The prepared statement of Mr. Muris appears as a submission for the record.]

Chairman HATCH. Thank you, Chairman Muris. We appreciate it, and we have appreciated the work you have done on this and the FTC has done.

We will go to Mr. Troy.

STATEMENT OF DANIEL E. TROY, CHIEF COUNSEL, U.S. FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MARYLAND

Mr. TROY. Thank you, Mr. Chairman. It is characteristic of your modesty that you referred to the law we are discussing today as Waxman–Hatch. Let me assure you, though, that everyone at the FDA talks about it as Hatch-Waxman.

Chairman HATCH. I am sure that is going to make Henry really happy, I will tell you.

Mr. TROY. That is not my goal.

I also want to say what an honor it is to sit next to Chairman Muris, whose leadership in this area has really been very useful for the FDA. We have tried to work closely together with the FTC, and I think it is fair to say that at least from where we sit the relationship between the FDA and the FTC on a wide variety of counts has never been stronger.

I want to begin by stressing that Dr. McClellan's main goal for the FDA in this area is to promote innovation, while also promoting rapid access to low-cost, safe and effective generic drugs. Our recent improvements to the implementation of Hatch-Waxman are really just part of a set of FDA initiatives that will reduce drug costs, while again encouraging innovation by speeding up the drug development and approval process without compromising FDA's high standards for safety and effectiveness.

We are taking a lot of steps to reduce the time and cost of new drugs so people have wider access to safe and effective new drugs. You need the new drugs in order to ultimately have the generic drugs. And with respect to generics, we believe our recent rule changes will help. But far more important, other reforms in the generic approval process that were announced at the same time will shave months off the time to availability of generic drugs across the board.

Similarly, under Dr. McClellan's leadership, we have charted new pathways for improving inhaled and topical drugs that will potentially affect many products. These broad improvements in drug availability, both new drugs and generic drugs, will have a major impact on all patients, not just those affected by imperfections in the current law. With all due respect, we truly believe that the additional $13 million to the Office of Generic Drugs will make the biggest difference in the area of generic drug reform.

That said, since its enactment in 1984, Hatch-Waxman has become an extremely valuable tool in making medications more affordable to American citizens. Of course, you know this, Mr. Chairman. To date, FDA has approved more than 10,000 generic drug products, providing high-quality, lower-cost prescription drugs to millions of consumers.

Of course, there are two provisions that have been associated with some anticompetitive behavior—the submission of brand name drug patents for listing by FDA, and the role of those patents in generating 30-month stays in the approval of generic drugs while patent infringement issues are litigated.

I am not going to go over what Chairman Muris said, but essentially the way I conceptualize Hatch-Waxman is as a complex signaling mechanism between generics and innovators, where the innovators declare their set of relevant patents. And the generics, when they submit their abbreviated new drug applications, have to declare the status of their product vis-a-vis those patents. And then, of course, there is the 45-day provision and 30-month stay to allow time for the patent issues to be worked out.

Some have suggested that FDA should take a much more active role in policing the patents that go into the Orange Book. I want to make clear that we do not undertake an independent review of the patents submitted by the NDA sponsor. We have tried in our new rule to make it clear which patents must and must not be listed, and to have a beefed-up declaration.

But as we understand the statute, it requires us to publish patent information on approval of the NDA, thus making the agency's role ministerial, and courts have so held. I think that one of the signal features of Hatch-Waxman is that generic and innovator firms are supposed to resolve their disputes about patent listings

and about patents in general in private litigation in the courts, where the expertise really resides with respect to patent questions.

We therefore strongly believe that FDA should not be asked to, or expected to review drug patents because we do not have the expertise to make these assessments. And we believe, for reasons that my written testimony goes into greater detail, that it would actually fail to speed the availability of generic drugs. We would end up in litigation, rather than litigation being worked out between the generics and the innovators.

As I mentioned, we really commend the FTC for their comprehensive study on these issues. It has been enormously useful to us. The factual information in the report was very valuable in our own discussions on the generic drug approval process.

Of course, the FTC recommended only one 30-month stay be allowed for infringement disputes over patents listed in the Orange Book before the filing of the ANDA. We agree that there should be one 30-month stay. We recognize, as our new rule says, that recently more ANDAs have been the subject of 30-month stays than in years past, and that more patents on average are now being litigated per generic drug application than in the past.

But we would note that the FTC report, number one, did not say how the single 30-month stay should be implemented. We tried to do it through dealing with the statute as it currently is, and we think we did so successfully, but we are happy to talk about that. We note that the FTC report recognized that we do not have the capacity to review the appropriateness of patent listings.

As you know and as you said, on June 12 we announced our final regulations that will streamline the process for making safe, effective generic drugs available to consumers. We expect that rule to save patients over $35 billion in drug costs over 10 years. We also think it will avoid unnecessary litigation and protect the process of developing new breakthrough drugs.

Brand name drug manufacturers will be limited, as you have said, to only one 30-month stay to resolve allegations that a generic drug maker is infringing a listed drug patent. Multiple 30-month stays will not be permitted. As I mentioned, we have tightened the requirements and increased the information required for drug patent submission and listings, and brand name drug manufacturers will not be allowed to delay access to generic drugs by submitting additional patents for listing in the Orange Book for drug packaging or other minor matters not really related to effectiveness.

The required submissions include patent information on active ingredients, drug formulations and composition, and approved uses of the drug. There is a much more detailed signed attestation accompanying the patent submission that is required, and we say on the declaration that false statements in the attestation can lead to criminal charges. We think these actions will significantly reduce opportunities to list inappropriate patents just to prevent access to low-cost generic alternatives.

We are pleased to note again, as you mentioned, that last week the Senate Committee on Health, Education, Labor, and Pensions unanimously reported legislation on accelerating access to generic drugs. We recognize and appreciate Chairman Gregg's leadership

in achieving the bipartisan agreement with the original sponsors of the bill.

We are pleased that this proposed legislation has key ideas embodies in FDA's regulation to improve access to generic drugs, and that it doesn't include some of the most problematic provisions of S. 812, which passed the Senate last year.

Not surprisingly, in this complex, very technical area of the law, we have concerns with the workability of that draft that we believe must be resolved for the legislation to achieve its intended effect. I know of no more of the law in which the law of unintended consequences operates with more force than this one.

We are working with the sponsors and other members to address various technical and policy issues. We are actively addressing the issues that have been raised by brand name and generic companies about the operation of the statute. We continue to work very, very hard to implement the Hatch-Waxman amendments as best we can, given the statutory text, the history of the legislation, as well as the numerous court challenges.

You know, it is sometimes liberating to know that no matter what you do, you are going to get sued. It frees you to try and do the right thing. In doing so, FDA has tried to maintain a balance between protecting innovation in drug development and in expediting the approval of lower-cost generic drugs.

I appreciate the opportunity to discuss these issues with you and I am happy to answer your questions.

[The prepared statement of Mr. Troy appears as a submission for the record.]

Chairman HATCH. Well, thank you.

Let me begin with Chairman Muris. It has been my experience that Government reports usually just simply gather dust. So let me start by congratulating you and your agency for producing a report that appears to be gaining more and more traction with policymakers.

In addition to the two major recommendations we have already talked about, your report also contains three minor recommendations. Could you please briefly describe for the Committee or provide for the record, if you wish, what these three minor recommendations are, what their status is with respect to acceptance within the administration and implementation, and how our Committee might best assist you with them if we decide they have merit?

Mr. MURIS. Yes, and thank you again, Mr. Chairman, for your kind words about the FTC. We made three minor recommendations about the 180-day exclusivity triggers. The first one was that commercial marketing, which is one of the triggers, includes generic marketing of a branded product. That is in the Gregg-Schumer bill.

The second is that the court decision trigger be a decision of the district court, which is the current rule. That is not in the Gregg-Schumer bill; it identifies they have the circuit court. Although there are clearly countervailing arguments on both sides of that issue, we think from the standpoint of consumers the district court rule is better. It provides the appropriate incentives, although we recognize that in some cases it could work a hardship on generics. It is a question of looking across the total of the circumstances and

balancing what we think is in consumers' best interest, which is the fundamental lodestone of FTC action.

Finally, the study's third recommendation was that dismissal of a declaratory judgment action be a decision of the court to trigger the 180 days. The D.C. Circuit in *Teva* held that a dismissal for lack of case or controversy would trigger the generic's exclusivity period. That is not in Gregg-Schumer. We would recommend that this provision be added to Gregg-Schumer.

Chairman HATCH. Okay, thank you.

Mr. Troy, what is your opinion of whether we should view the 30-month stay provisions of S. 1225, if enacted, as superseding, complementing, or having some other relationship with the recently finalized FDA rule?

Mr. TROY. Well, we believe that our rule has addressed the issue of single 30-month stays. Our rule does not address at all some of the other things that are addressed in S. 1225, in particular the 180-day exclusivity. I think a lot of the fixes that are talked about with respect to S. 1225 with respect to the 180 days are things that we might not—we haven't taken a hard look at this, but we might not be able to do by rule, as we felt we were able to change the prior interpretation because we thought the language was ambiguous and change the prior interpretation from multiple 30-month stays to single 30-month stays.

That said, again, without conceding that legislation is necessary because we don't believe legislation is necessary, if Congress were to codify a workable single 30-month stay provision, it is obviously easier to defend legislation than it is to defend a change in interpretation in the rule. But it has got to be workable, and our main concern—and we have been making very good progress working on a bipartisan basis with the staff—our main concern is to make sure that it is workable because this is a very complex area of law. It is very technical.

Again, I will go back a number of times to the law of unintended consequences. In part, because of our experience in trying to administer Hatch-Waxman, we see things that others might not because of our immense experience with—and it is not mine; it is the people on my staff, many of whom you know. There is no end to the originality of the arguments that are made in this area. The dollars are very large, the issues are extremely well-lawyered.

So we see pitfalls and traps in many different places, and so we have been trying to work with the staff, again we think in a way that has been making progress, to try and address those concerns.

Chairman HATCH. You may have referred to this briefly, but what, if any, of the patent listing and the 30-month stay provisions of the rule would need to be revisited if legislation is patterned after the outlines of S. 1225?

I will give you an example. For example, does the final rule limit the 30-month stay to those patents listed prior to the submission of the abbreviated new drug application, the ANDA?

Mr. TROY. Not in all cases, no. What the rule says is that there is one 30-month stay per ANDA. But if there is no paragraph IV certification with respect to the initial NDA, if you will, when the ANDA is filed, if there is a later listed patent and it is the first four, then you could have a 30-month stay. Let me suggest that

that is likely to be a relatively—in fact, extremely infrequent occurrence.

But let me say that the other two parts of our rule, tightening up on the patent declaration and making clear which patents must and must not be listed in the Orange Book, we think have already, to be immodest, made the world better by addressing the concerns that the FTC has raised and by providing clarity in this area and by limiting the opportunities for gaming.

If S. 1225 were to pass in this or any of the forms that are being discussed, those two parts of the rule would continue to operate, and again would continue to make the world better. Legislation codifying a single 30-month stay would clearly supersede, if you will, that part of the rule that says single 30-month stay because Congress will have directly spoken to the precise question at issue. Again, that aspect of the rule would presumably be, if the legislation were passed, superseded.

Chairman HATCH. Mr. Bradshaw, I have some questions and comments for you on one of the important matters in this.

Of course, Chairman Muris and Mr. Troy, you can comment, if you wish, on any of these questions.

As you know, some, including Boyden Gray, former White House Counsel under Bush I, have questioned the constitutionality of proposed Section 271(e)(5) of Title 35 as created by S. 1225. This section provides that the failure to bring a patent infringement action establishes a case or controversy sufficient to confer subject matter jurisdiction for a declaratory judgment action in Federal court. I understand that equally respected attorneys take a different view than Mr. Gray, and I know that the Department has not completed its analysis of this language.

Now, given that the so-called technical amendments package may affect this provision, it is possible that we may have to ask you to review different language at some point. I wonder if your research to date has turned up any other similar provision in the U.S. Code.

STATEMENT OF SHELDON T. BRADSHAW, DEPUTY ASSISTANT ATTORNEY GENERAL, OFFICE OF LEGAL COUNSEL, DEPARTMENT OF JUSTICE, WASHINGTON, D.C.

Mr. BRADSHAW. Thank you, Mr. Chairman. I am pleased to be with you today to discuss constitutional concerns surrounding S. 1225, the Greater Access to Affordable Pharmaceuticals Act.

On the specific language regarding the declaratory judgments in Section 271, we do not yet have a definitive position on whether cases brought pursuant to it would satisfy the Article III case or controversy requirement. I do have several general observations that I would make.

The requirement of an actual case or controversy, as set forth in the Declaratory Judgment Act, is constitutionally compelled rather than statutorily required. As such, like other Article III requirements—for example, standing—it cannot simply be granted by Congress, but must be satisfied by the plaintiffs.

I have not had an opportunity to fully examine this legislation or compare it with existing legislation. More importantly, we would like to see the package that contains the technical fixes which we

have not yet seen before we opined on that subject. But I would lead with those general observations that the actual case or controversy requirement is constitutionally compelled rather than statutorily required. And as a result, Congress can't simply create a case or controversy by statute, but the plaintiffs must establish the constitutional requirements for bringing the case.

Chairman HATCH. I would also note that the FDA final rule contains an informative discussion of how adoption of the one, and only one 30-month stay policy might affect declaratory judgment actions. If I read this discussion correctly, I think the FDA concluded that it was not a barrier even without the case or controversy provision contained in S. 1225.

Am I correct on that, Mr. Troy?

Mr. TROY. I am not an expert in this area, in part because it really has more to do with patent law. But we believe that in most cases—I think in virtually every case, a declaratory judgment suit for invalidity would lie. Whether a suit for infringement, or declaratory judgment with respect to infringement would lie if the innovator hasn't taken any action is an issue.

The courts haven't articulated a standard with respect to that. I am certainly not going to opine. I haven't really thought seriously about the constitutional issue. I would defer to the Justice Department on that. But what we have tried to say is that we believe that there can be mechanisms for the generic to get the kind of certainty that it may want before it goes to market.

Let's be clear that in many areas of industry people go to market and they run the risk of a lawsuit for patent infringement. That happens all the time. I could go into the pen-making business and if I am infringing on somebody's patent, I could be sued for patent infringement.

Generics, for good reasons, want more certainty than that before they launch, and so the question is can they get it. And we believe that, again, so long as they make sure that they do not run afoul of the FTC's concerns about competition, there may well be ways that we again articulated in the final rule for the generic to write to the innovator and say—this is outside the context of a 30-month stay where the notice is not a requirement—to write to the innovator and say, here is what we are doing, we invite you to sue us.

So the point is there may be ways for the generic to induce the kind of lawsuit and the kind of certainty. If the innovator is written and takes no action, then query whether or not there is a reasonable apprehension of suit.

Chairman HATCH. I would highlight, Mr. Bradshaw, the fact that the FDA pointed out in the 1999 Teva case that the D.C. Circuit found that no case or controversy existed when a patent-holder drug company disavowed an intent to sue. Now, absent this intent, the court could not find the requisite reasonable apprehension of suit.

I wonder if you have any preliminary thoughts on the case or controversy language of S. 1225, including what factors you need to analyze, and so forth. I also hope that the Department might be able to suggest ways to avoid any constitutional problematical language as work on the legislation continues.

Mr. BRADSHAW. Sure, and I understand again that one of the technical fixes under consideration may, I have been told, do that, in fact. But you are right in citing the D.C. Circuit case that the general test that courts have emphasized is whether there is a reasonable apprehension of an infringement suit as sort of the touchstone of justiciability in a case under the Declaratory Judgment Act.

As a result, the applicant in this case would need to have a reasonable apprehension that the patent-holder might bring an infringement suit in order to have an actual case or controversy for purposes of the declaratory judgment action. And if there was a case like the facts in the D.C. Circuit where the patent-holder expressly stated that, in fact, they would not bring an infringement action, it may be difficult for an applicant under those facts to establish an actual case or controversy.

Chairman HATCH. I hope you will get us your opinion as soon as possible.

Mr. BRADSHAW. We are in the process of working with the administration in formulating the administration's views on the constitutional questions, and just as soon as we receive a copy of the different technical fixes, we will go about reviewing them.

Chairman HATCH. Now, as the Department looks more closely at how S. 1225 reforms civil justice proceedings, you may very well have further comments on the bill. And if that is the case, I would like you to communicate your concerns to the Committee as soon as possible, okay?

Mr. BRADSHAW. Yes.

Chairman HATCH. Let me just ask you, is the Department currently looking at any other aspects of S. 1225, and if so, what are you examining?

Mr. BRADSHAW. Well, as you are aware, Mr. Chairman, the Office of Legal Counsel advises the administration on the constitutionality of all legislation that is introduced in Congress. So as a matter of course, our office is reviewing S. 1225 for constitutionality and we are in the process of advising the administration on our views.

Without going into any details on what we have advised people within the administration, because that process is still ongoing, I would note that others have raised questions related to whether or not portions of the bill are impermissibly retroactive. Again, like the Article III question, we have not yet taken a definitive position on that.

Chairman HATCH. All right.

For Mr. Muris and Mr. Troy, in its statement of administration policy opposing the McCain-Schumer bill of last year, the White House cited its fear that S. 812 might encourage excessive litigation. I am concerned that the unique and, in my view, not fully justified advantage granted to first filers with respect to the 180-day marketing exclusivity incentive may already be encouraging earlier lawsuits of dubious merit.

FDA"s shared exclusivity policy also, it seems to me, plays a role in this dynamic. I have seen the June 2 issue of the Pink Sheet that came out which contains an article detailing that the incredible pressure to be the first to file a paragraph IV challenge might

result in a marked increase in willful infringement cases. The article described a case in which a Federal court ruled against a generic firm which filed an ANDA application before obtaining outside counsel opinion on either non-infringement or invalidity.

To me, one of the most perplexing features of both S. 812 from last year and the new bill, S. 1225, is the almost unbelievable advantage given first filers of generic drug applications. As you know, prior to the D.C. Circuit's Mova decision in 1997, FDA had required a generic challenger to successfully defend against the patent claim of an innovator company.

Now, from a policy perspective, why should a mere first filer be treated better than a party who actually wins a lawsuit? And if we are to legislate in this area, why don't we consider overriding Mova and reinstate the old successful defense requirement?

We will start with you, Mr. Muris, or either one.

Mr. MURIS. The Commission in its report doesn't view the 180 days as a reward for successfully defending a patent suit. We view it as an incentive to file the ANDA in the first instance.

Now, I know there are some proposals to actually avoid the shanty town problem of people in line to file, and I am sure Mr. Troy will address those. But we think that it does create an incentive to go ahead and be clever and innovative. And if you are so clever and innovative that the branded decides it can't even sue you, then we think so much the better.

In fact, of the 104 brand-name drugs that we looked at, in 75 the brand did go ahead and sue the generic for infringement, but in 29 it didn't. From the standpoint of an incentive, we believe the generic, which develops a product and avoids litigation, such as in those 29 cases, should benefit from the exclusivity.

Mr. TROY. We certainly agree with you about S. 812 and we thought that it would unduly induce too much litigation, and the administration opposed S. 812.

With respect to the 180-day exclusivity, what Chairman Muris was referring to is right now there are sometimes limousines, sometimes vans, sometimes cars, sometimes tents in the Metro North parking lots that come days, weeks, and in some cases even months in advance of a particular date. Why we should reward someone because they camp out longer in the parking lot is a good question as a matter of policy. It is a good question.

That said, we are working, we think, very productively with the staff on S. 1225 to embody more of a, shall we say, use it or lose it approach so that someone can't park their exclusivity. The FTC has done a great job in ensuring that people can't park their exclusivity.

We don't have an official administration policy or position on whether or not you should or shouldn't have 180 days of exclusivity. We certainly think that the question of whether or not you should get this reward for being the first and simply the one to stand on line the longest is a worthy policy question and is worth talking about and thinking about.

But as I understand all of the discussions that have been going on, I think that there is a recognition that that is an issue, and there have been some very good solutions that have been talked about and thought about in order to try and solve that problem.

Chairman HATCH. With respect to completing the rulemaking in less than 1 year from proposed to final rule, it is quite an accomplishment, and you and your staff, I think, need to be commended for that.

Mr. TROY. Thank you, Mr. Chairman.

Chairman HATCH. That is great. Frankly, I am somewhat envious, to be honest with you, because it has been almost 10 years since the Dietary Supplement Health and Education Act passed Congress and there are still no final rules specifying good manufacturing practices for those products.

Mr. TROY. We got out the proposal.

Chairman HATCH. I don't want any excuses. That is fine.

I am pleased that you adopted a one, and only one 30-month stay principle, but I wonder how you respond to those in the R and D industry, whose shenanigans with multiple stays started the trouble in the first place, who say the way you drafted the final rule allows the system to be gamed by ANDA applicants.

Here is the type of example some have raised with me with respect to the new FDA rule. Suppose there were two patents prior to the filing of an ANDA, one compound patent and one formulation patent. A generic applicant may intend to challenge both, but initially files a paragraph III certification on the compound patent and a paragraph IV certification on the formulation patent.

Determining that the generic firm has invented around the formulation patent, the generic decides not to pursue the paragraph IV litigation. Instead, the ANDA applicant decides to allege invalidity and converts the paragraph III certification on the compound to a full-blown paragraph IV challenge.

The question is this: Under the rule, is the 30-month stay already used up, and if so, doesn't this open the door to such tactics?

Mr. TROY. I think, in part, it depends on whether or not it is within the first 45 days and whether litigation was commenced. But let me say that there is no way, through rulemaking or through legislation, to avoid all opportunities for gaming. We tried within the limits of the law to plug as many of the loopholes as we could.

I have never participated in a process like this, but we would have 10 or 15 staffers in a room with the text of the rule up on a screen and we would go through it, all of us, word by word in order to look for opportunities that might be seized upon to be gamed in an effort to try and say this argument might be made here, this argument might be made here.

We tried as best we could to cut down on all opportunities for gaming. We did not succeed in cutting down all opportunities for gaming because no legislation is so good, no rule could be so good as to cut down all opportunities for gaming because there are unforeseen circumstances and unintended consequences.

We think we have addressed 80, 85, maybe 90 percent of the loopholes that are obvious and that we have seen in the past within the limits of the law. This hypothetical that you have mentioned was raised to us. We again tried to address it within the context of what happens in the first 45 days. If there is all sorts of switching, FDA, like all administrative agencies, retains authority with

respect to shams. If people are really playing games, we think we have authority to deal with that.

But I am not smart enough, and the 20 people sitting around the room aren't smart enough and far-sighted enough, despite all of our expertise and experience, to see every single situation that could be gamed. And that said, there were obviously limits to what we could do because we are an administrative agency trying to implement the statute.

But, again, we are having much the same discussions and the same experience with respect to the legislation because either way you tilt it, you can't write it so clearly that there are no opportunities for gaming. And there is going to be tilting one way or the other, and some of the issues that come up are on which side of the table do you want to run the risk of gaming.

I think the best way to approach this, frankly, is to say, well, on this side with respect to this issue, we are going to run a little more risk of gaming on this side, and on this side for this issue we are going to run a little bit more risk of gaming on this side. Hopefully, you end up with something that has some degree of balance.

Chairman HATCH. Mr. Muris, let me ask you one last question. Section III–C of your testimony discusses some of your enforcement activities with respect to settlements between generic manufacturers.

Do you think it is advisable to work with Senator Leahy to consider amending the text of the Drug Competition Act to require the reporting to FTC and DOJ of certain potentially troublesome generic-generic or brand name-to-brand name agreements, in addition to the generic-brand name agreements that the bill currently addresses?

Mr. MURIS. We had 20 brand-generic agreements. We only had six generic-generic agreements, but some of those did raise potential anticompetitive problems. In fact, we did bring one case involving that. It is certainly not something to which I would object. Based on the evidence, it was not as big a problem as the brand-generic.

Chairman HATCH. For the two of you, I have one last question that has come up, and that is I want to bring out in this question some of the complex policy tradeoffs at play in this area.

First, would one of you be so kind as to give the Committee a short explanation of what a polymorph is? And please make it a discussion at the level of polymorphs for dummies, okay?

Mr. TROY. The most simple example of what a polymorph is is water, ice, and steam; same molecule, different form. It is all H20.

Chairman HATCH. Second, I note from comments that the FTC submitted to FDA in December that the FTC's view of the proper treatment of polymorph patents is somewhat different from the FDA's.

Could each of you briefly describe your agency's views on the legal and policy arguments regarding the appropriateness of listing polymorph patents in the FDA Orange Book?

Mr. MURIS. Let me put this in context. With the single 30-month stay, if it is upheld by courts or put in the legislation, this problem becomes much less important. The problem with these later listed patents, however would be eliminated by a single 30-month stay.

We found questionable patenting practices in six of the eight later listed patents in which there is a court decision or FTC action. Those listings have been found to be questionable.

Second, the FDA did address to some extent our concern—and we appreciate that—in changes they made from the proposed rule to the final rule, and I am sure Mr. Troy will explain those, and I will defer to him on the empirical evidence. But I think they believe it would have taken care of most of the problems that we saw.

There was a difference of opinion in how to read the statute and that was the source of our disagreement. Obviously, under our system and under the Chevron decision, they have the final say in reading their statute, subject to court review, and that court review gives fairly significant deference.

Chairman HATCH. Thank you.

Mr. Troy?

Mr. TROY. I just want to reiterate what Chairman Muris said. We think that the single 30-month stay and the tightened-up patent declaration and making clear which patents must and must not be listed will substantially alleviate this issue because the incentive to come in with later listed patents, if you have a single 30-month stay, largely falls away. So that is the first point.

This was, at least for me, the most vexing issue as a policy matter and as a legal matter in the rule because, on the one hand, the FTC articulated an interpretation that said the inquiry for listing is different than the inquiry for bioequivalence. The other argument was made, well, that is trying to have it both ways. You can't say it is not the same when it comes to listing, but it is the same when it comes to approval. You are trying to have it both ways. There is a bias here.

And so we really struggled with the issue and ultimately we felt that because the courts have, in fact, given us so much flexibility with respect to interpreting what is the same, we thought that we diminished our legal risk by going in that direction. I am not going to suggest that it was an easy decision. It was probably the most hotly debated issue internally with respect to the rule.

But we think that particularly with the change from the proposal to the final which says that—it sort of squares the circle, if you will, and says if you are maintaining that it is the same, innovator, then you have to have done the work internally to prove that it is indeed the same; i.e., to have satisfied at least yourself and to be willing to certify that there is a degree of bioequivalence there.

We think that that is going to dramatically limit any opportunity for the indiscriminate listing of polymorph patents and gaming of the system even on its own, separate and apart from the fact that the single 30-month stay is going to reduce the incentives for the gaming with these later listed patents.

So it is a hard issue. I am not pretending it is not a difficult issue. We found the input of the FTC very helpful and very useful and we think we have come up with a solution that works.

Chairman HATCH. Well, thank you.

We will turn to Senator Schumer.

STATEMENT OF HON. CHARLES E. SCHUMER, A U.S. SENATOR FROM THE STATE OF NEW YORK

Senator SCHUMER. Well, thank you, Mr. Chairman, and I first want to thank you not only for holding this hearing, but for your leadership on this issue. I said this a while back that I think Hatch-Waxman was one of the great pro-consumer pieces of legislation of the last 25 years. Your authorship of it is a very important feather in your cap that I hope you wear proudly, and I am glad to see that you are still involved and interested in this issue, which I know you are from the last few years that we have been involved.

Chairman HATCH. Thank you so much. I appreciate that.

Senator SCHUMER. I also want to thank Senator Leahy, who has been involved, and together with you, Mr. Chairman, worked on the Drug Competition Act which the Senate passed last year.

Senator Leahy wanted to be here today, but couldn't, and I would just ask unanimous consent that his opening statement be put in the record.

Chairman HATCH. Without objection, and we will put any statements in the record.

Senator SCHUMER. Thank you, Mr. Chairman.

I would also like to thank Senator Gregg for his leadership in approaching me and bringing together Senators McCain and Kennedy, with whom I have worked on this issue in the past few years. Together, Judd and I, along with the others, have crafted a strong bipartisan bill which is now poised to pass the Senate, and I think has a real chance of making it through the House as well.

The bill which passed out of Committee unanimously last week achieves the goals of the original Schumer–McCain bill of closing loopholes in the law which I know we are hearing about from our witnesses today. But it does so my modifying certain provisions to address the concerns that kept its critics from supporting it last year, including my friend Senator Hatch, who is always giving me some good advice on how to deal with these kinds of issues.

Before I get into the discussion of the bill, I would like to talk about the issue and how far we have come in bringing these abuses to light over the last few years. Two years ago, Chairman Hatch called a hearing on this very same issue. At the time, we heard from the FDA, the FTC, and witnesses representing consumers and States who all shared their concern about ways in which the pharmaceutical industry was taking advantage of one of the most pro-consumer laws passed in decades, Hatch-Waxman.

The compromise that Senator Hatch and Congressman Waxman crafted was carefully done, intended to strike a balance and help save consumers billions of dollars, while rewarding brand name companies for their innovations. For years, the law worked to do exactly that, but as the profits became higher, and frankly it seemed to me as the pharmaceutical industry, the brand name industry, had a large number of blockbuster drugs that were about to expire, and with their worry that they couldn't replace them with other drugs that were just as profitable, they began to find ways around this law, instead of innovating new drugs, innovating new patents.

This is how America works; find a good lawyer and they will find a good loophole, and that is what happened. Companies began to

do that, and even, to boot, some of the generic companies were hardly blameless. They would make deals with the brand name company and say, give us some money and we will keep this drug off the market.

Congress began to look at all of these abuses 2 years ago with Chairman's Hatch. What has happened since then? First, the evidence mounted. In three additional hearings last year, Congress—this Committee, the Commerce Committee, the HELP Committee, the House Energy and Commerce Committee—heard how double-digit growth in drug costs and anticompetitive activity in the pharmaceutical industry has thrown not only citizens, but corporations, State Medicaid programs, and insurers into a tailspin as they struggle to pay for the drugs.

Then the FTC issued a report which documented abuse of several key loopholes in the law, creating barriers to generic entry. Most significantly, the report identified eight blockbuster drugs, representing billions of dollars in sales for which the brand companies listed patents late in the process and triggered the successive 30-month stays of generic competition.

The pharmaceutical companies have argued before Congress that these patents and the delays have been legitimate. Well, we have heard from the courts on five of these products, and so far in every single instance the courts have decided that these patents have been invalid or not infringed by the generic challenger. That doesn't sound too legitimate to me; zero for five is not a great batting record.

Let me illustrate with an example. The example is Paxil. This is a $2.1 billion drug used to treat obsessive-compulsive disorder. It has been in litigation since 1998. After the lawsuit began and the first 30-month stay was triggered, the brand company, Glaxo SmithKline, listed nine additional patents on the drug, which ended up triggering five additional 30-month stays.

Well, over the last year there have been court decisions on four of those patents. The patent which began this litigation was not found to be infringed upon by the generic, and the other three were found to be flat-out invalid. But the 30-month stays are still preventing the competition, costing consumers $3 billion.

So this is a problem; it is a real problem. We have now the State attorneys general banding together to bring multiple suits against pharmaceutical companies. They have secured hundreds of millions of dollars in damages. The administration, under the FDA, has issued new regulations.

Before I get into the substance of what we are talking about here—and I appreciate the opportunity to speak at some length, Mr. Chairman—I would make a plea to the pharmaceutical industry. You make a great product, you save people's lives. This is a good thing. You deserve a rate of return that is a fine rate of return. I don't dispute that. There are some who do. I don't. But the bottom line is, by overdoing it on these patents, you are ruining your goodwill.

This is not an area where we are talking about price controls. It is not even an area we are talking about where American consumers pay for the research for the whole world. You have gotten what you are supposed to get on these patents, a large amount of

profitability. God bless you. You have come out with a good product.

But then to come up with some of these changes and say they are perfectly legitimate and say you are really just searching for better ways to serve the consumer—everyone in America knows that is bunk. This is one area where the pharmaceutical industry should say, hey, we want to work with you to keep a legitimate rate of return for wonderful drugs that save people's lives, but not abuse it, and because we have made so much money and we have to make more money. That is truly a heartfelt plea.

We have some good companies in New York that employ thousands of people and they do good things. But the bottom line is don't kill the goose that laid the golden egg, because that is what happening here. Instead of the pharmaceutical industry being held in high esteem, which it was a decade ago, you are beginning to lose it, and some of it is just because the prices are high and people don't like that. But some of it is because you are abusing certain privileges, and you are not doing it in any area more so than generic drugs. So join with us. Don't fight us.

I do want to say, Mr. Chairman, I think the proposal that Senator Gregg and I have put together is fair and balanced, and again saying to the pharmaceutical industry, I know you are not fighting us head-on, but I am going to fight weakening this bill. I am not going to allow loopholes, not going to allow lack of enforcement. I am not going to let someone say, because you can pluck out some lawyer somewhere who says something might be unconstitutional, leave this bill denuded. I feel very strongly about this.

So where are we now? The proposal we have put together makes it easier for less expensive generic drugs to be sold in pharmacies. It will significantly reduce overall drug spending in the U.S. by billions. And yet, as Senator Gregg is always mindful, it will continue to allow innovation. It will continue to say to the industry, create something good and new and you are going to get an excellent rate of return on it.

I think you have gone over what the bill does, but basically the bottom line—I used to call it Mitch Daniels' dream. Now, maybe we will have to call it Josh Bolton's dream. It is free-market, it is pro-consumer, and it doesn't cost the Government a penny. In fact, it will save the Government money.

The bill provides a critical complement to the work the FDA has done in clarifying its regulations on patent listing, but it goes much further. The FDA, to its credit, has said we can't do it all; lots of this needs statute, when they came out with their proposed regulations which are now in effect, I guess.

Chairman HATCH. Senator, your time is up. My problem is I have to be out of here at twenty-five after eleven.

Senator SCHUMER. Let me just say quickly, on this chart, the FDA regulations get you up to here. We take you all the way through, and there are many other things that need to be done and the FDA regulations are not sufficient.

I am going to ask that the rest of my statement be placed in the record, Mr. Chairman, because I know you are busy.

Chairman HATCH. Without objection.

[The prepared statement of Senator Schumer appears as a submission for the record.]

Senator SCHUMER. I have a question or two, but I will defer.

Chairman HATCH. We will keep the record open for written questions for any Senator on the Committee, and I will have some, I think.

Senator SCHUMER. I will submit written questions to speed this along, Mr. Chairman.

Chairman HATCH. Would you do that, because I am pressured and I have to be out of here?

Senator SCHUMER. Yes, no problem.

Chairman HATCH. I want to thank the three of you for being here. I think this has been an excellent time, and I want to personally tell all three of you how much I respect you and the work that you do. I think you are just terrific and you are doing great work.

Mr. Troy, you have brought a breath of fresh air out there at FDA, in my opinion, and I just want to compliment you for it.

You know how highly I think of you, Mr. Muris.

Justice Department, get us that information as soon as you can, will you?

Mr. BRADSHAW. Yes.

Chairman HATCH. Well, thank you so much. We appreciate you being here.

Mr. MURIS. Thank you very much, Mr. Chairman.

Mr. TROY. Thank you.

Chairman HATCH. Now, we will go to our next panel. Our first witness on the second panel is my friend, Howard Metzenbaum, former Senator from Ohio, representing the Consumer Federation of America.

We welcome you back, Howard. You used to be a member of this Committee and we look forward to hearing your testimony.

The second panelist will be Ms. Kathleen Jaeger, President of the Generic Pharmaceutical Association. We are very happy to have you here, Ms. Jaeger.

Finally, we will hear from Bruce Kuhlik, General Counsel to the Pharmaceutical Research and Manufacturers of America.

It is possible that these three witnesses might not see eye to eye on all of these issues, so it will be interesting to hear what you have to say. We will put your full statements in the record. If you can summarize very quickly, I would appreciate it, in 5 minutes, because I have to leave here in about ten minutes. So if you can, I would appreciate it.

Senator Metzenbaum, we will turn to you first.

STATEMENT OF HOWARD M. METZENBAUM, FORMER UNITED STATES SENATOR, AND CHAIRMAN, CONSUMER FEDERATION OF AMERICA, WASHINGTON, D.C.

Mr. METZENBAUM. As one who participated in so many filibusters with you, it would be difficult for me to summarize that briefly, but I will do the best I can, Mr. Chairman.

Chairman HATCH. Listen, I recognize that well.

[Laughter.]

Mr. METZENBAUM. Mr. Chairman and Senator Schumer, it is good to be back at the Judiciary Committee. My name is Howard

Metzenbaum. I serve as Chairman of the Consumer Federation of America. I appreciate your invitation to offer my comments, which I am presenting on behalf of the Consumer Federation and Consumers Union, which publishes Consumer Reports magazine.

The FTC report detailed the many specious tactics used by drug companies to stall or thwart public access to less expensive generic drugs. It is actually outrageous that the same companies that charge Americans the highest drug prices in the industrialized world would use secret payoffs, flimsy legal maneuvers, and backroom deals to eliminate generic competition, line their pockets, and harm consumers.

Every time a drug company blocks a safe generic drug from getting into the hands of the American people, they are not only placing a tax on the uninsured, the sick and the elderly, but are doing untold harm to millions of Americans. These outrageous attempts to keep drug prices high are particularly disgraceful because they undermine the effectiveness of one of your major achievements, Mr. Chairman, the Hatch-Waxman Act. You and Congressman Waxman provided great and wise leadership in drafting a law that carefully balances the need for drug innovation and affordability.

Hatch-Waxman dramatically increased access to generic drugs, saved consumers billions of dollars, and ensured that the drug manufacturers have adequate patent protection to justify substantial investment in research and development. However, in recent years, as a number of top-selling blockbuster drugs were due to come off patent, brand drug manufacturers have used their political muscle and legal resources to block generic drugs from coming to market.

When crass legislative efforts to pass unjustified patent extensions failed in Congress in the late 1990's, the drug industry turned to their platoon of legal talent for help. They filed late patent claims just before a drug was to come off patent. Sometimes, those claims had nothing to do with the therapeutic equivalent of a generic drug, such as the shape or color of a pill.

They filed numerous nuisance lawsuits on the same drugs for violation of those late patents. This triggered Hatch-Waxman's 30-month stay on the approval of a generic drug, and they made secret payments to some generic companies to keep generic alternatives off the market. To the drug industry, I say you should be ashamed of your conduct. You have abused the free market system.

I will not discuss the additional $13 million that has been appropriated to the FDA for speedy approval of generic drugs. Let me assure you, however, that we strongly support that appropriation if it helps reduce the 20 months, on average, that it takes now for approval of a generic drug.

I would like to comment briefly on two of the major responses to the FTC's report that we have seen—the Senate bipartisan legislation that was reported out of the HELP Committee last week and the FDA's new generic rule. These two responses are somewhat complementary, but the Senate legislation will be far more effective in protecting the public from the range of abuses I have detailed.

First, it would limit the ability of brand name drug manufacturers to block generics through multiple 30-month stays. The bill would generally allow a drug company to receive only one stay per

drug. The FDA rules on restrictions on multiple stays, by contrast, are far weaker and would allow brand drug companies to continue to game the system.

Second, generic drug companies would have the right to assure that their drugs are not in violation of any patents before going to market by seeking a declaratory judgment.

Third, the bill would take some moderate steps to reduce nuisance patent lawsuits. Unfortunately, however, this is one area where the bipartisan compromise will not be as effective as legislation passed overwhelmingly by the Senate last year.

Unlike last year's bill, the compromise does not provide as many disincentives to stop brand drug companies from filing unjustified late patents. I will give you an example. Last year's bill gave generic companies a private right of action to de-list improper patents, and it didn't allow the brand drug companies to file an infringement lawsuit unless the patent in question was listed at the time the drug was approved.

Regarding the FDA's generic rule which took effect last week, it has some strengths. For instance, it requires brand drug companies to provide more information about the patents they are listing. Overall, however, it is a disappointment. It is unlikely to reduce the many anticompetitive tactics that have been cited today. Even worse, it requires the listing of some new categories of patents. This may actually encourage brand drug companies to play patent hanky-panky once again.

In closing, let me reiterate, Mr. Chairman and Senator Schumer, that the pharmaceutical industry has repeated used improper delaying tactics to thwart access to generic drugs. Their activities have been and continue to be shameful. This is not only a threat to the pocketbooks of many Americans, but to their health, and it is blight upon the free enterprise system. When faced with high drug costs, many people will go without needed medication or reduce the consumption of these drugs below the prescribed label.

Senator Hatch and Senator Schumer, I urge you and members of the Committee to support actively the bipartisan compromise legislation that will soon reach the floor. Although the bill is not as strong as legislation that passed the Senate last year, I applaud the efforts of Senators Kennedy, Schumer, McCain, and Gregg to find a compromise that will decrease drug costs and increase the flow of cheaper generic drugs to Americans in need.

I am very grateful to you, Mr. Chairman, for the opportunity to appear before your Committee. I think that we need action promptly and I am hopeful that we will see such action provided by your leadership, Senator Schumer, and other members of this Committee.

[The prepared statement of Mr. Metzenbaum appears as a submission for the record.]

Chairman HATCH. Thank you, Senator Metzenbaum.

We will turn to you, Ms. Jaeger, and take your testimony at this time.

STATEMENT OF KATHLEEN D. JAEGER, PRESIDENT AND CHIEF EXECUTIVE OFFICER, GENERIC PHARMACEUTICAL ASSOCIATION, WASHINGTON, D.C.; ACCOMPANIED BY JOHN YOO, PROFESSOR OF LAW, UNIVERSITY OF CALIFORNIA AT BERKELEY, BERKELEY, CALIFORNIA

Ms. JAEGER. Thank you, Mr. Chairman, distinguished members of the Committee. My name is Kathleen Jaeger. I am the President and CEO of the Generic Pharmaceutical Association. On behalf of GPhA and its members, I especially want to thank you, Mr. Chairman, for your leadership on this issue as the original author of the landmark Hatch-Waxman Act, and for convening this hearing today.

We applaud the Senate and the administration for their commitment to a package of administrative and legislative measures that, if taken together and not weakened, will make American health care more affordable.

As you know, Senate bill 1225, the Greater Access to Affordable Pharmaceuticals Act, sponsored by Senators Gregg, Schumer, McCain, and Kennedy, was unanimously passed out of the Senate HELP Committee last week. We echo the President's intention to work with both the House and the Senate on this legislation to make certain that prescription drugs are more affordable to the American public.

We believe that Senate bill 1225 will remove some of the most serious market barriers to generic competition. We also believe that the administration's regulatory initiatives, coupled with the compromise bill, will make American health care more affordable and provide consumers with timely access.

But given that, instead of actually discussing the actual compromise that is on the table, you have raised some very important issues with respect to constitutionality with respect to the declaratory judgment provision, and out of respect for your time, Mr. Chairman, I ask that Mr. John Yoo, who is here today, actually speak to that issue. Mr. Yoo served as General Counsel to this Committee under your chairmanship from 1995 to 1996. In addition, Mr. Yoo has clerked for Supreme Court Justice Clarence Thomas, and currently is a visiting fellow at the American Enterprise Institute and a professor of law at Berkeley.

With your permission, may I turn over the floor to Mr. John Yoo, please.

Chairman HATCH. Sure.

John, welcome back to the Committee. You are an old friend and a terrific law professor.

Mr. YOO. Thank you, Mr. Chairman, and I will just very quickly provide some advice to the Committee.

Chairman HATCH. Real quickly, though.

Mr. YOO. I hope that unlike past time when I worked for you, you actually listen to my advice a little bit this time.

[Laughter.]

Chairman HATCH. Well, I think we have heard enough from you.

[Laughter.]

Chairman HATCH. Go ahead.

Mr. YOO. Just on the two points of the Declaratory Judgment Act and the 30-month stay provision, it is my view that both provisions

are constitutional. The Declaratory Judgment Act is a more difficult issue than the 30-month stay provision, but this is exactly the kind of circumstance that the Declaratory Judgment Act was passed to address, cases where potential patent infringers need to bring a suit to get some kind of declaration about their rights because the patent-holder might not bring suit.

In fact, when Congress passed the bill in 1934, it specifically discussed this exact situation, and the Supreme Court, as you know, 3 years later in the Aetna case upheld the Declaratory Judgment Act.

The only potential issue is whether the case law of the Federal Circuit and this reasonable apprehension test raises any doubt about the constitutionality of this legislation. There are a number of reasons why I don't think it does. One is that the reasonable apprehension test itself may not be an interpretation of the Article III case or controversy requirement, but might be an exercise of the Federal Circuit's prudential discretion not to hear certain kinds of suits.

Second, I think it is perfectly appropriate for Congress to articulate a standard that might be odds with a lower Federal court if it wants the Supreme Court to determine finally whether this is a proper interpretation of the Article III case or controversy requirement.

On the 30-month stay, just very quickly, a 30-month stay provision is just a change in the procedures that are used to enforce a Federal property right. It doesn't actually affect the Federal property right itself. As the Supreme Court has said most recently in the *Plout* case, Congress has full authority to make changes in cases that have not been finally decided by the Article III courts, and the procedures and even the substantive rights at issue, so long as, again, there has been no final determination of those rights and a final judgment by the Article III courts.

Thank you, Mr. Chairman.

Chairman HATCH. We would appreciate any further scholarship you can give us on this in writing. It would be helpful to us because it is a matter of concern.

Ms. JAEGER. We would be happy to.

Chairman HATCH. Thank you both for being here.

[The prepared statement of Ms. Jaeger appears as a submission for the record.]

Chairman HATCH. Mr. Kuhlik, you are the last one and if you could keep your remarks—I am in trouble here, but if you can keep your remarks within 5 minutes, I would appreciate it.

STATEMENT OF BRUCE N. KUHLIK, SENIOR VICE PRESIDENT AND GENERAL COUNSEL, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, WASHINGTON, D.C.

Mr. KUHLIK. I have been crossing out as you go along. Thank you, Mr. Chairman.

I am Bruce Kuhlik, Senior Vice President and General Counsel of the Pharmaceutical Research and Manufacturers of America. We are pleased to have the opportunity to testify this morning.

Landmark legislation passed by Congress in 1984, commonly known as the Hatch-Waxman Act, has fulfilled its twin goals of ex-

pediting generic drug entry and encouraging pharmaceutical innovation. By any measure, the law has been an enormous boon to the generic industry, as Chairman Muris explained this morning.

For 3 years, though, we have had a debate over the need for new legislation. Until the FTC issued its report last year, however, the debate lacked any shared understanding of the facts. We were therefore pleased when the FTC issued its report last July. The report confirmed that the Hatch-Waxman Act works. Out of approximately 6,000 generic drugs approved since 1984, the FTC identified only 8 instances in which innovator companies had received so-called multiple 30-month stays. Even accepting the view that there is something wrong with these stays, a law that works 5,992 times out of 6,000 is a law that works and, in our view, works well.

The FTC called for two principal changes in the law: first, a limitation on 30-month stays to patents listed with FDA in the Orange Book before an ANDA is filed, and, second, a requirement that certain agreements between innovator and generic companies be reported to the FTC.

A number of legislative and regulatory proposals have emerged since last July, none limited to the comparatively modest suggestions made by the FTC. First, the Senate passed a bill last year, Senate bill 812, that would have created a new cause of action for patent de-listing, cut off the right to a 30-month stay for a broad universe of patents, subjected innovator companies to a 45-day statute of limitations, and forfeited patent enforcement rights altogether in certain cases.

Mr. Chairman, you testified last year that this bill, quote, "goes too far without a compelling demonstration of systemic abuse, and it upsets the carefully crafted balance," unquote, in the law.

Next, FDA proposed new Hatch-Waxman regulations last October which were issued in final form last week. The FDA rule attempts to address the multiple 30-month stay question within the confines of the current law, but we believe that it raises significant technical concerns regarding generics' ability to avoid any 30-month stay. In this regard, the agency said in the preamble, and Mr. Troy indicated as well this morning that it cannot completely prevent manipulation of the rule.

Also, last week the HELP Committee marked up a bill, S. 1225, that attempts to address the 30-month stay issue precisely as the FTC suggested. This bill, we believe, is a significant improvement over previous legislative proposals and is close, Mr. Chairman, I think, to what you have suggested as appropriate.

Senator Schumer, we congratulate you, Senator Gregg, and the other sponsors of this bill for your leadership in developing it.

In its present form, however, as marked up by the committee, the bill does present significant technical and workability concerns regarding operation of the 30-month stay. Mr. Troy discussed some of those earlier this morning. It also goes beyond the FTC report by addressing other issues in a problematic fashion. We have heard discussion this morning of the constitutional issues raised by the declaratory judgment provision.

As Mr. Boyden Gray said, former White House Counsel, quote, "The bill takes the absence of a live case or controversy and defines it as a live case or controversy," unquote. We look forward to hear-

ing what the Justice Department has to say about that constitutionality provision.

The bill would also limit the availability of treble damages in certain cases involving willful infringement by generics. At a time when generic abuses of the statute are growing, it would make little sense to discriminate against pharmaceutical patent-holders by curtailing the remedies for this sort of behavior.

Where does this leave us? We believe that the FTC report vindicates our longstanding view that legislation to amend the Act in a manner adverse to research and innovation is unnecessary. At the same time, the technical concerns presented by both the FDA rule and S. 1225 as marked up counsel in favor of addressing the complex 30-month stay issue correctly. We would be pleased to work on a bipartisan basis toward this goal, with the priority of seeing such a bill passed and signed into law as quickly as possible.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Kuhlik appears as a submission for the record.]

Chairman HATCH. Thank you so much.

I am going to turn to Senator Schumer for just a very short statement.

Senator SCHUMER. I will submit written questions.

Chairman HATCH. We will all submit written questions, and we have got a lot of questions.

Senator SCHUMER. Thank you, Mr. Chairman. I just wanted to say Senator Gregg and I spent a lot of time working on this compromise and we consulted numerous constitutional experts on the declaratory judgment provision in the bill. They were virtually unanimous that there was no constitutional problem, so I am not worried about it.

That is what I wanted to say for the record, Mr. Chairman.

Chairman HATCH. Well, thank you.

I want to thank each of you for being here. Mr. Yoo, please submit any scholarship you can on this, and I know you will, knowing you, and you also, Mr. Kuhlik. These are important issues. I think you, Ms. Jaeger, have represented the generic industry well.

Senator Metzenbaum, the consumers of America are well represented by you. There is no question about that. I still remember you rushing onto the floor at the last minute trying to stop this effort, talking to Ralph Nader and trying to stop Hatch-Waxman. But I had slipped it through on you before you got in there, and you just immediately went back to work to stop some other things you thought were wrong.

But I will tell you it is a privilege to have you here in the Judiciary Committee room again, and it is a privilege to have your testimony. So we appreciate you taking the time to do it.

Thank you all for being here.

With that, we will recess and I will get to my next meeting.

[Whereupon, at 11:34 a.m., the Committee was adjourned.]

[Submissions for the record follow.]

SUBMISSIONS FOR THE RECORD

Prepared Statement of
The Federal Trade Commission

Before the

Committee on Judiciary
United States Senate

Washington, D.C.

June 17, 2003

I. Introduction

Mr. Chairman, I am Timothy J. Muris, Chairman of the Federal Trade Commission. I am pleased to appear before the Committee today to testify on behalf of the Commission regarding competition in the pharmaceutical industry, and, in particular, findings and recommendations in the July 2002 FTC Study of Generic Drug Entry Prior to Patent Expiration.[1]

Advances in the pharmaceutical industry continue to bring enormous benefits to Americans. Because of pharmaceutical innovations, a growing number of medical conditions often can be treated more effectively with drugs and drug therapy than with alternative means *(e.g.*, surgery). The development of new drugs is risky and costly. Expenditures on pharmaceutical products continue to grow. The growth of prescription drug spending at retail outlets has "exceeded that of other health services by a wide margin, increasing 17.3 percent in 2000, the sixth consecutive year of double-digit growth."[2] Pharmaceutical expenditures are thus a concern not only to individual consumers, but also to government payers, private health plans, and employers.

To address the issue of escalating drug expenditures, and to ensure that the benefits of pharmaceutical innovation would continue, Congress passed the Hatch-Waxman Amendments[3]

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[1] The written statement represents the views of the Federal Trade Commission. My oral presentation and responses are my own and do not necessarily reflect the views of the Commission or of any other Commissioner.

[2] K. Levit, C. Smith, C. Cowan, H. Lazenby & A. Martin, "Inflation Spurs Health Spending in 2000," 21:1 *Health Affairs* 179 (2002), citing data from the Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, of which the authors are members.

[3] Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)).

("Hatch-Waxman" or "the Amendments") to the Food, Drug and Cosmetic Act ("FDC Act").[4] Hatch-Waxman established a regulatory framework that sought to balance incentives for continued innovation by research-based pharmaceutical companies and opportunities for market entry by generic drug manufacturers.[5] Without question, Hatch-Waxman has increased generic drug entry. The Congressional Budget Office estimated that, by purchasing generic equivalents of brand-name drugs, consumers saved $8-10 billion on retail purchases of prescription drugs in 1994 alone.[6] With patents set to expire within the next several years (or those that have recently expired) on brand-name drugs having combined U.S. sales of almost $20 billion,[7] the already substantial savings are likely to increase dramatically.

Yet, in spite of this remarkable record of success, the Amendments have also been subject to some abuse. Although many drug manufacturers – including both brand-name and generic companies – have acted in good faith, others have attempted to "game" the system, securing greater profits for themselves without providing a corresponding benefit to consumers. Responding to these abuses, the Senate last year passed S. 812, the Greater Access to Affordable Pharmaceuticals Act introduced by Senators McCain and Schumer and S. 754 , the Drug Competition Act, introduced by Senator Leahy. In addition, last October, the Food and Drug Administration ("FDA") proposed rules to limit certain of these abuses,[8] and just last week the FDA finalized these proposals. This testimony will describe the Commission's past and present response to the anticompetitive conduct of some drug manufacturers.

The Commission has pursued numerous antitrust enforcement actions affecting both brand-name and generic drug manufacturers.[9] In addition, the Commission released a study

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[4] 21 U.S.C. § 301 *et seq.*

[5] *See infra* note 15 and accompanying text. The Amendments also were intended to encourage pharmaceutical innovation through patent term extensions.

[6] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998) ("CBO Study"), *available at* <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0>.

[7] *Id.* at 3.

[8] Department of Health and Human Services, Food and Drug Administration, Applications for FDA Approval to Market a New Drug; Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed, 67 Fed. Reg. 65,448 (Oct. 24, 2002).

[9] *See, e.g., Bristol-Myers Squibb Co.*, Dkt. No. C-4076 (Apr. 14, 2003) (consent order); *Biovail Corp. and Elan Corp. PLC*, Dkt. No. C-4057 (Aug. 20, 2002) (consent order); *Biovail Corp.*, Dkt. No. C-4060 (Oct. 2, 2002) (consent order); *Abbott Laboratories*, Dkt. No. C-3945;

entitled "Generic Drug Entry Prior to Patent Expiration" ("FTC Study") in July 2002. That study examines whether the conduct that the FTC has challenged represented isolated instances or is more typical of business practices in the pharmaceutical industry and whether certain provisions of Hatch-Waxman are susceptible to strategies to delay or deter consumer access to generic alternatives to brand-name drug products.[10] The Commission has gained expertise regarding competition in the pharmaceutical industry through other means as well. The Commission staff has conducted empirical analyses of competition in the pharmaceutical industry, including in-depth studies by the staff of the Bureau of Economics.[11] The Commission's efforts have included filing comments with the FDA regarding the competitive aspects of Hatch-Waxman implementation,[12] as well as previous testimony before Congress.[13] Furthermore, individual

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Geneva Pharmaceuticals, Inc., Dkt. No. C-3946 (May 22, 2000); *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293; *FTC v. Mylan Laboratories, Inc. et al.*, 62 F. Supp. 2d 25 (D.D.C. 1999).

[10] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

[11] Bureau of Economics Staff Report, Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (Mar. 1999), *available at* <http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf>; David Reiffen and Michael R. Ward, *Generic Drug Industry Dynamics*, Bureau of Economics Working Paper No. 248 (Feb. 2002) ("Reiffen and Ward"), *available at* <http://www.ftc.gov/be/econwork.htm>.

[12] *FDA: Applications for FDA Approval to Market a New Drug; Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed*, Comment of the Federal Trade Commission (Dec. 23, 2002) ("30-Month Stay Comment"), *available at* <http://www.ftc.gov/be/v030002.pdf> (recommending modifications to FDA proposed rule on patent listing requirements and providing suggestions to the proposed patent declaration); *FDA: Citizen Petition*, Comment of the Staff of the Bureau of Competition and of the Office of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Mar. 2, 2000), *available at* <http://www.ftc.gov/be/v000005.pdf> (recommending modifications to the FDA's Proposed Rule on citizen petitions intended to discourage anticompetitive abuses of the FDA's regulatory processes); *FDA: 180-Day Marketing Exclusivity for Generic Drugs*, Comment of the Staff of the Bureau of Competition and of the Office of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Nov. 4, 1999) ("Marketing Exclusivity Comment"), *available at* <http://www.ftc.gov/be/v990016.htm> (recommending that the FDA's Proposed Rule on 180-day marketing exclusivity be modified to limit exclusivity to the first ANDA filer and to require filing of patent litigation settlement agreements).

[13] Testimony of the Federal Trade Commission before the Committee on Energy and Commerce, Subcommittee on Health, United States House of Representatives, *Study of Generic Drug Entry Prior to Patent Expiration* (Oct. 9, 2002), *available at*

Commissioners have addressed the subject of pharmaceutical competition before a variety of audiences, both to solicit input from affected parties and to promote discussion about practical solutions.[14]

After reviewing the relevant Hatch-Waxman provisions, this testimony will address the Commission's vigorous enforcement of the antitrust laws with respect to branded and generic drug competition. One type of conduct involves allegedly anticompetitive settlements between brand-name and generic companies. Because the Commission became aware of and challenged such settlements first, this testimony refers to those matters as "first-generation litigation." Other, more recent types of conduct, such as allegedly improper Orange Book listings and potentially anticompetitive settlements between generic manufacturers themselves, are the subject of the Commission's "second-generation actions."

Next, the testimony will address the Commission's industry-wide study of generic drug entry prior to patent expiration. An understanding of the Commission's cases in this area will provide the framework for the issues that the Commission examined in this study. The testimony also provides a brief overview of how the FDA's new regulations will hep curb some of the problems identified by the FTC Study.

II. Regulatory Background: The Hatch-Waxman Drug Approval Process

A. The Hatch-Waxman Balance

One of the stated purposes of Hatch-Waxman is to "make available more low cost generic

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<http://www.ftc.gov/os/2002/10/genericstestimony021009.pdf>; Testimony of the Federal Trade Commission before the Committee on Commerce, Science, and Transportation, United States Senate, *Competition in the Pharmaceutical Industry* (Apr. 23, 2002), *available at* <http://www.ftc.gov/os/2002/04/pharmtestimony.htm>; Testimony of the Federal Trade Commission before the Committee on the Judiciary, United States Senate, *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements* (May 24, 2001), *available at* <http://www.ftc.gov/os/2001/05/pharmtstmy.htm>.

[14] *See, e.g.*, Sheila F. Anthony, *Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property* (June 1, 2000), *available at* <http://www.ftc.gov/speeches/anthony/sfip000601.htm>; Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes* (Nov. 3, 2000), *available at* <http://www.ftc.gov/speeches/leary/learypharma.htm>; Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II* ("Part II") (May 17, 2001), *available at* <http://www.ftc.gov/speeches/leary/learypharmaceutical settlement.htm>; Timothy J. Muris, *Competition and Intellectual Property Policy: The Way Ahead*, at 5-6 (Nov. 15, 2001), *available at* <http://www.ftc.gov/speeches/muris/intellectual.htm>.

drugs."[15] The concern that the FDA's lengthy drug approval process was unduly delaying market entry by generic versions of brand-name prescription drugs motivated Congress's passage of the Amendments. Because a generic drug manufacturer was required to obtain FDA approval before selling its product, and could not begin the approval process until any conflicting patents on the relevant brand-name product expired, the FDA approval process essentially functioned to extend the term of the brand-name manufacturer's patent. To correct this problem, Congress provided in the Amendments that certain conduct related to obtaining FDA approval, which would otherwise constitute patent infringement, would be exempted from the patent laws.

Congress continued to regard patent protection, however, as critical to pharmaceutical innovation and an important priority in its own right. Hatch-Waxman thus represented a compromise: an expedited FDA approval process to speed generic entry balanced by additional intellectual property protections to ensure continuing innovation. As one federal appellate judge explained, the Amendments "emerged from Congress's efforts to balance two conflicting policy objectives: to induce brand-name pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."[16]

Pursuant to the FDC Act, a brand-name drug manufacturer seeking to market a new drug product must first obtain FDA approval by filing a New Drug Application ("NDA"). At the time the NDA is filed, the NDA filer must also provide the FDA with certain categories of information regarding patents that cover the drug that is the subject of its NDA.[17] Upon receipt of the patent information, the FDA is required to list it in an agency publication entitled "Approved Drug Products with Therapeutic Equivalence," commonly known as the "Orange Book."[18]

Rather than requiring a generic manufacturer to repeat the costly and time-consuming NDA process, the Amendments permit the company to file an Abbreviated New Drug Application ("ANDA"), which references data that the "pioneer" manufacturer has already submitted to the FDA regarding the brand-name drug's safety and efficacy. Under the ANDA process, an applicant must demonstrate that the generic drug is "bioequivalent" to the relevant brand-name product.[19] The ANDA must contain, among other things, a certification regarding

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[15] H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

[16] *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting) (citations omitted). *See also Warner-Lambert v. Apotex*, 316 F.3d 1348, 1358 (Fed. Cir. 2003).

[17] 21 U.S.C. § 355(b)(1).

[18] *Id.* § 355(j)(7)(A).

[19] *Id.* § 355(j)(2)(A)(iv).

each patent listed in the Orange Book in conjunction with the relevant NDA.[20] One form of certification is a "Paragraph IV certification," asserting that the patent in question is invalid or not infringed.[21]

Filing a Paragraph IV certification potentially has significant regulatory implications, as it is a prerequisite to the operation of two provisions of the statute. The first of these is the automatic "30-month stay" protection afforded to patent holders and the NDA filer – most typically, brand-name companies. An ANDA filer that makes a Paragraph IV certification must provide notice to both the patent holder and the NDA filer, including a detailed statement of the factual and legal basis for the ANDA filer's assertion that the patent is invalid or not infringed.[22] Once the ANDA filer has provided such notice, a patent holder wishing to take advantage of the statutory 30-month stay provision must bring an infringement suit within 45 days.[23] If the patent holder does not bring suit within 45 days, the FDA may approve the ANDA as soon as other regulatory conditions are fulfilled.[24] If the patent holder does bring suit, however, the filing of that suit triggers an automatic 30-month stay of FDA approval of the ANDA.[25] During this period, unless the patent litigation is resolved in the generic's favor, the FDA cannot approve the generic product.

The second significant component of Hatch-Waxman is the "180-day period of exclusivity." The Amendments provide that the first generic manufacturer to file an ANDA containing a Paragraph IV certification is awarded 180 days of marketing exclusivity, during which the FDA may not approve a subsequent applicant's ANDA.[26] The 180-day exclusivity period increases the economic incentives for a generic company to be the first to file an ANDA, because the generic applicant has the potential to reap the reward of marketing the only generic product (and, thus, to charge a higher generic price until more generic products enter).[27] Through

[20] *Id.* § 355(j)(2)(A)(vii).

[21] *Id.* § 355(j)(2)(A)(vii)(IV).

[22] *Id.* § 355(j)(2)(B). Although the patent holder and the NDA filer are often the same person, this is not always the case. Hatch-Waxman requires that all patents that claim the drug described in an NDA be listed in the Orange Book. Occasionally, this requires an NDA filer to list a patent that it does not own.

[23] *Id.* § 355(j)(5)(B)(iii).

[24] *Id.* For example, the statute requires the ANDA applicant to establish bioequivalence. *Id.* § 355(j)(2)(A)(iv).

[25] *Id.* § 355(j)(5)(B)(iii).

[26] *Id.* § 355(j)(5)(B)(iv).

[27] There has been litigation over what acts trigger the 180-day period of exclusivity. *See* FTC Study, *supra* note 10. This study is discussed in detail below.

this 180-day provision, the Amendments provide an increased incentive for companies to challenge patents and develop alternatives to patented drugs.[28] The 180-day period is calculated from the date of the first commercial marketing of the generic drug product or the date of a court decision declaring the patent invalid or not infringed, whichever is sooner.[29] Of course, during the 180 days, the brand-name company is still marketing its brand-name product. After the 180 days, subject to regulatory approvals, other generic companies can enter the market. When additional generic competitors enter the market, competition drives the price for the generic product below the price established by the first generic entrant that was entitled to the 180-day exclusivity.[30]

B. Competitive Implications

The 30-month stay and the 180-day period of exclusivity were both parts of the Hatch-Waxman balance. The imposition of a 30-month stay of FDA approval of an eligible ANDA could forestall generic competition during that period of time. The 180-day period of exclusivity can, in some circumstances, limit the number of generic competitors during this 180-day period. Over the past few years the Commission has observed through its investigations, law enforcement actions, and industry-wide study that some brand-name and generic drug manufacturers may have "gamed" these two provisions, attempting to restrict competition beyond what the Amendments intended. The next section of this testimony discusses the Commission's efforts to investigate vigorously and to prosecute such abuses.

III. Promoting Competition Through Antitrust Enforcement

A. First-Generation FTC Litigation: Settlements Between Brand-Name Companies and Generic Applicants

Studies of the pharmaceutical industry indicate that the first generic competitor typically enters the market at a significantly lower price than its brand-name counterpart, and gains substantial share from the brand-name product in a short period of time.[31] Subsequent generic entrants may enter at even lower prices and cause the earlier entrants to reduce their prices. These are precisely the procompetitive consumer benefits that the Amendments were meant to facilitate.

This competition substantially erodes the profits of brand-name pharmaceutical products. Although successful generic applicants are profitable, their gain is substantially less than the loss of profits by the brand-name product, because of the typical difference in prices between brand-

[28] *See Granutec, Inc. v. Shalala*, 139 F.3d 889, 891 (4th Cir. 1998).

[29] 21 U.S.C. § 355(j)(5)(B)(iv).

[30] *See* Reiffen and Ward, *supra* note 11.

[31] *See* CBO Study, *supra* note 6; *see generally* Reiffen and Ward, *supra* note 11.

name and generic products. As a result, both parties may have economic incentives to collude to delay generic entry. By blocking entry, the brand-name manufacturer may preserve monopoly profits. A portion of these profits, in turn, can be used to fund payments to the generic manufacturer to induce it to forgo the profits it could have realized by selling its product. Furthermore, by delaying the first generic's entry – and with it, the triggering of the 180 days of exclusivity – the brand-name and first-filing generic firms can sometimes forestall the entry of other generic products.

The Commission has challenged conduct by firms that allegedly have "gamed" the Hatch-Waxman framework to deter or delay generic competition. Our "first generation" of such matters involved agreements through which a brand-name drug manufacturer allegedly paid a generic drug manufacturer not to enter and compete. The complaints in these cases also alleged that the brand-name company used the generic company's rights to the 180-day exclusivity under Hatch-Waxman to impede entry by other generic competitors. Two leading cases illustrate the Commission's efforts in the area: *Abbott/Geneva* [32] and *Hoechst/Andrx*.[33] The Commission resolved both cases by consent order.[34] Very recently, the Commission settled another case involving a drug settlement in which the brand-name company, Bristol-Myers, allegedly had paid a generic drug manufacturer $72.5 million to abandon its challenge to a Bristol-Myers patent and to stay off the market until the patent expired.[35]

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[32] *Abbott Laboratories*, Dkt. No. C-3945 (May 22, 2000) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/05/c3945complaint.htm>; *Geneva Pharmaceuticals, Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/05/c3946complaint.htm>.

[33] *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm>.

[34] The consent order in *Abbott Laboratories* is available at <http://www.ftc.gov/os/2000/03/abbot.do.htm>. The consent order in *Geneva Pharmaceuticals* is available at <http://www.ftc.gov/os/2000/03/genevad&o.htm>. The consent order in *Hoechst/Andrx* is available at <http://www.ftc.gov/os/2001/05/hoechstdo.pdf>.

In another matter, *Schering-Plough,* the Commission resolved all claims against one of three respondents, American Home Products ("AHP"), by issuing a final consent order. *Schering-Plough Corp.*, Dkt. No. 9297 (consent order as to AHP issued Apr. 2, 2002), *available at* <http://www.ftc.gov/os/2002/02/ahpdo.pdf>. The case against the other two respondents is on appeal before the Commission. *See Schering-Plough Corp.*, Dkt. No. 9297 (July 2, 2002) (initial decision)(appeal pending), *available at* <http://www.ftc.gov/os/2002/07/scheringinitialdecisionp1.pdf>.

[35] *Bristol-Myers Squibb Company*, Dkt. No. C-4076, *available at* <http://www.ftc.gov/os/caselist.c4076.htm>.

B. Second-Generation FTC Actions: Improper Orange Book Listings

Our "second generation" of enforcement activities has involved allegations that individual brand-name manufacturers have delayed generic competition through the use of improper Orange Book listings[36] that trigger a Hatch-Waxman provision prohibiting the FDA from approving a generic applicant for 30 months. Brand-name drug manufacturers may sometimes act strategically to obtain *more than one* 30-month stay of FDA approval of a particular generic drug. The Commission recently described the consumer harm that occurs when an invalid patent forms the basis of such 30-month stays.[37]

1. Clarification of *Noerr-Pennington* Doctrine: *In re Buspirone*

Unlike the settled cases discussed above, which involved alleged collusion between private parties, an improper Orange Book listing strategy involves unilateral abuse of the Hatch-Waxman process itself to restrain trade. Such conduct has raised *Noerr-Pennington* antitrust immunity issues, an area of longstanding Commission interest. The *Noerr* doctrine[38] provides antitrust immunity for parties "petitioning" government. While the *Noerr* doctrine is an important limitation on the antitrust laws that protects the right of parties to communicate with government entities, some courts have interpreted the doctrine too broadly in ways that are inconsistent with Supreme Court precedent and harm consumers.

To address the concern that the *Noerr* doctrine was being interpreted too expansively, a *Noerr-Pennington* Task Force of Commission staff began work in June 2001. One of the objectives of the Task Force was to examine certain aspects of the *Noerr* doctrine, such as the scope of "petitioning" conduct and the continuing existence of a misrepresentation exception to *Noerr* immunity.

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[36] The Commission first raised concerns about the potential anticompetitive impact of improper Orange Book listings in *American Bioscience, Inc. v. Bristol-Myers Squibb Co., et al.*, Dkt. No. CV-00-08577 (C.D. Cal. Sept. 7, 2000). *See* Federal Trade Commission Brief as *amicus curiae, available at* <http://www.ftc.gov/os/2000/09/amicusbrief.pdf>. In that case, the parties sought court approval of a settlement containing a specific factual finding that Bristol-Myers was required to list American Bioscience's patent of Bristol-Myers's branded drug Taxol in the Orange Book. The Commission was concerned that the court's approval of the settlement would amount to a judicial finding that the patent met the statutory requirements for listing in the Orange Book and would prejudice parties who might later challenge the listing.

[37] *See* Memorandum of Law of Federal Trade Commission As *Amicus Curiae* Concerning Torpharm's Cross Motion for Entry, *SmithKline Beecham Corporation et al. v. Apotex Corporation, Apotex, Inc. and Torpharm, Inc., and Other Related Cases* (E.D. PA, Jan. 28, 2003), *available at* <http://www.ftc.gov/ogc/briefs/smithklineamicus.pdf>.

[38] The *Noerr* doctrine was first articulated as an interpretation of the Sherman Act in *Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) and *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965).

One of the first potential abuses the Task Force considered was the improper listing of patents in the FDA's Orange Book. Pursuant to current policy, the FDA does not review patents presented for listing in the Orange Book to determine whether they do, in fact, claim the drug product described in the relevant NDA.[39] Instead, the FDA takes at face value the declaration of the NDA filer that the listing is appropriate. As a result, an NDA filer acting in bad faith can successfully list patents that do not satisfy the statutory listing criteria. Once listed in the Orange Book, these patents have the same power to trigger a 30-month stay of ANDA approval as any other listed patent, thereby delaying generic entry and potentially costing consumers millions of dollars without valid cause.

In January of last year, private lawsuits relating to Bristol-Myers's alleged monopolization through improper listing of a patent on its brand-name drug BuSpar[40] presented the Commission with an opportunity to clarify the *Noerr* doctrine. Specifically, plaintiffs alleged that, through fraudulent filings with the FDA, Bristol-Myers caused that agency to list the patent in question in the Orange Book, thereby blocking generic competition with its BuSpar product, in violation of Section 2 of the Sherman Act.[41]

Bristol-Myers responded to these allegations by filing a motion to dismiss that raised, principally, a claim of *Noerr-Pennington* immunity. Given the importance of the issue to competition in the pharmaceutical industry, the Commission filed an *amicus* brief opposing the motion to dismiss.[42] On February 14, 2002, the court issued an opinion denying Bristol-Myers's

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[39] *See* 21 C.F.R. § 314.53(f); *see also* Abbreviated New Drug Application Regulations – Patent and Exclusivity Provisions, 59 Fed. Reg. 50338, 50343 (1994) ("FDA does not have the expertise to review patent information. The agency believes that its resources would be better utilized in reviewing applications rather than reviewing patent claims."); Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28910 (1989) ("In deciding whether a claim of patent infringement could reasonably be asserted . . . the agency will defer to the information submitted by the NDA applicant.").

[40] *In re Buspirone Patent Litigation/In re Buspirone Antitrust Litigation*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) ("*In re Buspirone*"). Some of the same plaintiffs previously had brought suit under the FDC Act, requesting that the court issue an order compelling Bristol-Myers to de-list the objectionable patent. Although plaintiffs prevailed at the district court level, the Federal Circuit reversed that decision, holding that the FDC Act did not provide a private right of action to compel de-listing of a patent from the Orange Book. *See Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323, 1331-32 (Fed. Cir. 2001). Although free to do so, Bristol-Myers chose not to re-list the patent after the Federal Circuit decision.

[41] 15 U.S.C. § 2.

[42] Memorandum of Law of *Amicus Curiae* Federal Trade Commission in Opposition to Defendant's Motion to Dismiss, *available at* <http://www.ftc.gov/os/2002/01/busparbrief.pdf>. (The Commission argued that Orange Book filings are not "petitioning activity" immune from antitrust scrutiny.)

immunity claim and accepting most of the Commission's reasoning on the *Noerr-Pennington* issue.[43]

In light of the *Buspirone* decision, the *Noerr-Pennington* doctrine may not prove as large an obstacle to using the antitrust laws to remedy improper Orange Book filings as some may have anticipated. It is worth noting, and indeed emphasizing, that *Buspirone* does not mean that all improper Orange Book filings will give rise to antitrust liability. Any antitrust liability must be predicated on a showing of a violation of substantive antitrust law. *Buspirone* makes it clear, however, that Orange Book filings are not *immune* from those laws or *exempt* from their scrutiny.

The Commission's own, more recent, law enforcement action against Bristol-Myers also raised a significant *Noerr-Pennington* issue. Specifically, the case provided an opportunity for the Commission to emphasize the continuing existence of a "pattern exception" to *Noerr*. As the Analysis to Aid Public Comment that accompanied the proposed consent agreement explains, "the logic and policy underlying the Supreme Court's decision in *California Motor Transport* . . . support the application of a pattern exception for BMS's alleged pattern of conduct . . . and thus provide a separate reason to reject *Noerr* immunity here."[44] *California Motor Transport*[45] involved allegations that a group of trucking companies had agreed to routinely oppose *every* application of additional motor carrier operating rights filed with state or federal agencies. After evaluating the competitive implications of this conduct, the Court concluded that "a pattern of baseless, repetitive claims . . . effectively barring respondents from access to the agencies and courts . . . cannot acquire immunity by seeking refuge under the umbrella of 'political expression.'"[46] In the *Bristol-Myers* Analysis, the Commission contends that this pattern exception to *Noerr* should not be limited to repetitive lawsuits, but rather should be applicable to any predatory, repetitive use of government process. Specifically, the Analysis states that "[j]ust

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[43] *In re Buspirone,* 185 F.Supp.2d at 367-77.

[44] *Bristol-Myers Squibb Co.*, File Nos. 001-0221, 011-0046, 021-0181 at 11 (Mar. 7, 2003) (Analysis to Aid Public Comment) *available at* <http://www.ftc.gov/os/2003/03/bristolmyersanalysis.htm>.

[45] *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972).

[46] *Id.* at 513. *See also Primetime 24 Joint Venture v. National Broadcasting Co.*, 219 F.3d 92, 101 (2d Cir. 2000) (district court should not have dismissed on *Noerr* grounds plaintiff's allegations that defendants violated Section 1 of the Sherman Act by filing repeated, baseless signal strength challenges under the Satellite Home Viewer Act); *USS-POSCO Indus. v. Contra Costa County Bldg. & Constr. Trades Council*, 31 F.3d 800, 811 (9th Cir. 1994) ("When dealing with a series of lawsuits, the question is not whether any one of them has merit – some may turn out to, just as a matter of chance – but whether they are brought pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival.").

as the repeated filing of lawsuits brought without regard to the merits . . . warrants rejection of *Noerr* immunity," so too does the repeated filing of knowing and material misrepresentations with the PTO and FDA.[47]

2. Enforcement Action Against Improper Orange Book Listings: *Biovail* (Tiazac) and *Bristol-Myers Squibb* (BuSpar, Taxol, and Platinol)

In October 2002, the Commission issued a consent order against Biovail Corporation,[48] settling charges that Biovail illegally acquired an exclusive patent license and wrongfully listed that patent in the Orange Book for the purpose of blocking generic competition to its brand-name drug Tiazac. This was the Commission's first enforcement action to remedy the effects of an allegedly improper, anticompetitive Orange Book listing.

Prior to the events giving rise to the Commission's complaint, Biovail already had triggered a 30-month stay of FDA final approval of Andrx's generic Tiazac product, by commencing an infringement lawsuit against Andrx. Andrx prevailed in the courts, however, so that the stay would have been lifted by February 2001. According to the Commission's complaint,[49] Biovail, in anticipation of pending competition from Andrx, undertook a series of anticompetitive actions to trigger a new stay and maintain its Tiazac monopoly. Just before the stay was to terminate, Biovail acquired exclusive rights to a newly issued patent from a third party and listed that patent in the Orange Book as claiming Tiazac – thereby requiring Andrx to re-certify to the FDA and opening the door to Biovail's suit against Andrx for infringement of the new patent and commencement of a second 30-month stay.

The Commission's complaint alleged that Biovail's patent acquisition, wrongful Orange Book listing, and misleading conduct before the FDA were acts in unlawful maintenance of its Tiazac monopoly, in violation of Section 5 of the Federal Trade Commission Act[50] ("FTC Act"), and that the acquisition also violated Section 7 of the Clayton Act.[51] The consent order requires Biovail to divest the exclusive rights to their original owner with certain exceptions; to achieve dismissal with prejudice of any and all claims relating to enforcement of the patent in relation to Tiazac; and to refrain from any action that would trigger another 30-month stay on generic Tiazac entry. Further, the order prohibits Biovail from unlawfully listing patents in the Orange Book and requires Biovail to give the Commission prior notice of acquisitions of patents that it will list in the Orange Book for Biovail's FDA-approved products. These measures should not

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[47] *Bristol-Myers* Analysis to Aid Public Comment, *supra* note 44, at 16.

[48] *Biovail Corp.*, Dkt. No. C-4060.

[49] The Commission's complaint against Biovail is available at <http://www.ftc.gov/os/2002/04/biovailcomplaint.htm>.

[50] 15 U.S.C. § 45.

[51] *Id.* § 18.

only remedy Biovail's allegedly unlawful conduct, but also send a strong message that the Commission will act decisively to eliminate anticompetitive practices in the pharmaceutical industry.[52]

In a second, more recent case, the Commission alleged a decade-long pattern of anticompetitive acts by Bristol-Myers to obstruct the entry of low-price generic competition for three of Bristol-Myers' widely-used pharmaceutical products: two anti-cancer drugs, Taxol and Platinol, and the anti-anxiety agent BuSpar, as noted earlier. Bristol-Myers allegedly abused FDA regulations to block generic entry, misled the U.S. Patent and Trademark Office (PTO) to obtain unwarranted patent protection, and filed baseless patent infringement lawsuits to deter entry by generics. According to the FTC's complaint, Bristol-Myers' illegal conduct protected nearly $2 billion in annual sales at a high cost to cancer patients and other consumers, who – being denied access to lower-cost alternatives – were forced to overpay by hundreds of millions of dollars for important and often life-saving medications.

The FTC resolved these allegations through a consent order with Bristol-Myers that contains strong -- and in some respects unprecedented -- relief.[53] This consent order, among other restrictions, is designed to eliminate Bristol-Myers' alleged ability to abuse FDA regulations, and thereby reduce Bristol-Myers' incentive to engage in improper behavior before the PTO. The order includes a provision that prohibits Bristol-Myers from triggering a 30-month stay based on any patent Bristol-Myers lists in the Orange Book after the filing of an application to market a generic drug, and limits Bristol-Myers' ability to provide information about a patent to the FDA that is inconsistent with information it provided to the PTO.

C. Settlements Between Generic Manufacturers

Although agreements between first and second generic entrants have attracted significantly less attention to date, they too can raise competitive concerns and may draw antitrust scrutiny. As in the case of agreements between brand-name companies and generic applicants, the economic incentives to collude can be strong. Studies indicate that the first generic typically enters the market at 70 to 80 percent of the price of the corresponding brand[54] and rapidly secures as much as a two-thirds market share. The second generic typically enters at an even lower price and, like the first, rapidly secures market share. Collusion between the generic firms can thus be a means of preventing price erosion in the short term, though it may

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[52] The Commission also recently described the competitive harm of having invalid patents listed in the FDA's Orange Book in a case involving the drug product Paxil. *See* Memorandum of Law of Federal Trade Commission As *Amicus Curiae* Concerning Torpharm's Cross Motion for Entry, *SmithKline Beecham Corporation et al. v. Apotex Corporation, Apotex, Inc. and Torpharm, Inc., and Other Related Cases*, *supra* note 37.

[53] *Bristol-Myers Squibb Company*, Dkt. No. C-4076 (Apr. 14, 2003).

[54] *See* CBO Study, *supra* note 6; Reiffen and Ward, *supra* note 11, at 22.

become substantially less feasible if subsequent ANDAs are approved and additional competitors enter the market.

In August 2002, the Commission issued a consent order against two generic drug manufacturers to resolve charges that they entered into an agreement that unreasonably reduced competition in the market for a generic anti-hypertension drug.[55] According to the Commission's complaint, Biovail Corporation (Biovail) and Elan Corporation PLC (Elan) agreed not to compete in marketing 30 mg and 60 mg generic Adalat CC products, and that the agreement lacked any countervailing efficiencies.[56]

The order, which has a ten-year term, remedies the companies' alleged anticompetitive conduct by requiring them to terminate the agreement and barring them from engaging in similar conduct in the future.[57] The order maintains commercial supply of the incumbent generic Adalat products while the companies unwind their agreement, and eliminates the anticompetitive obstacles to entry of a second 30 mg and a second 60 mg generic Adalat CC product.

IV. The Commission's Industry-Wide Generic Drug Competition Study

A. Background and Introduction

In light of the questions its various generic drug investigations raised, the Commission proposed an industry-wide study of generic drug competition in October 2000. The FTC Study focused solely on the procedures used to facilitate generic drug entry *prior to* expiration of the patent(s) that protect the brand-name drug product – that is, generic entry through the procedures involving Paragraph IV certifications.[58] The Commission undertook the study for three reasons:

(1) To determine whether alleged anticompetitive agreements that relied on certain Hatch-Waxman provisions were isolated instances or more typical, and whether particular provisions of the Amendments are susceptible to strategies to delay or deter consumer access to generic alternatives to brand-name drug products;

(2) To respond to Representative Henry Waxman's request for the Commission to "investigate and produce a study on the use of agreements between and among pharmaceutical companies and potential generic competitors and any other strategies that may delay generic drug competition throughout the U.S."; and

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[55] *Biovail Corp. and Elan Corp. PLC*, Dkt. No. C-4057 (Aug. 15, 2003).

[56] The Commission's complaint against Biovail and Elan is available at <http://www.ftc.gov/os/2002/08/biovalcmp.pdf>.

[57] The consent order in the *Biovail/Elan* matter is available at <http://www.ftc.gov/os/2002/08/biovaldo.pdf>.

[58] The FTC Study does not address other procedures for generic entry.

(3) To ensure that there are no roadblocks in the way of generic competition for the substantial sales volume of brand-name drug products coming off patent in the next several years.[59] Brand-name companies seeking to protect the sales of brand-name drugs may have an incentive and ability to enter into agreements with would-be generic competitors, or engage in other types of activities, that would slow or thwart the entry of competing generic drug products.

In April 2001, the Commission received clearance from the Office of Management and Budget ("OMB") to conduct the study.[60] The Commission issued nearly 80 special orders – pursuant to Section 6(b) of the FTC Act[61] – to brand-name companies and to generic drug manufacturers, seeking information about certain practices that were outlined in the Federal Register notices that preceded OMB clearance to pursue the study.[62] The Commission staff focused the special orders on brand-name drug products that were the subject of Paragraph IV certifications filed by generic applicants. Only those NDAs in which a generic applicant notified a brand-name company with a Paragraph IV certification after January 1, 1992, and prior to January 1, 2001, were included in the FTC Study. The selection criteria resulted in 104 drug products, as represented by NDAs filed with the FDA, within the scope of the study and included so-called "blockbuster" drugs such as Capoten, Cardizem CD, Cipro, Claritin, Lupron Depot, Neurontin, Paxil, Pepcid, Pravachol, Prilosec, Procardia XL, Prozac, Vasotec, Xanax, Zantac, Zocor, Zoloft, and Zyprexa.

Responses from the 28 brand-name companies and nearly 50 generic applicants generally were completed by the end of 2001. The Commission staff compiled the information received to provide a factual description of how the 180-day marketing exclusivity and 30-month stay provisions affect the timing of generic entry prior to patent expiration. The FTC Study did not provide an antitrust analysis of each of the types of agreements submitted, nor did it examine other issues involved in the debate over generic drugs, such as bioequivalence or the appropriate length of patent restorations under Hatch-Waxman.

B. Findings: Litigation Frequency and Outcomes

The FTC Study sought to determine the frequency with which brand-name companies have triggered the 30-month stay provision by suing generic applicants for patent infringement within the required 45-day period. For 72 percent of drug products the study covered, brand-name companies initiated patent infringement litigation against the first generic applicant. There

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[59] National Institute for Health Care Management, *Prescription Drugs and Intellectual Property Protection* at 3 (Aug. 2000), *available at* <http:\\www.nichm.org/prescription.pdf>.

[60] The Commission was required to obtain OMB clearance before it could begin the study because the number of special orders to be sent triggered the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. Ch. 35, as amended.

[61] 15 U.S.C. § 46(b).

[62] *See* 65 Fed. Reg. 61334 (Oct. 17, 2000); 66 Fed. Reg. 12512 (Feb. 27, 2001).

was no suit in the other 28 percent, and the FDA has approved most of the generic products, thus allowing generic entry to occur. FDA approval of these ANDAs took, on average, 25.5 months from the ANDA filing date.

In 70 percent of the cases (53 of the 75 drug products) in which the brand-name company sued the first generic applicant, either there has been a court decision (30 of the 53 drug products) or the parties have agreed to a final settlement without a court decision on the merits of the patent infringement lawsuit (20 of the 53 drug products).[63] In the other 30 percent of the cases (22 of the 75 drug products), a district court had not yet ruled as of June 1, 2002.

Of all the patent infringement cases (with the first generic applicant) in which a court had rendered a decision as of June 1, 2002, generic applicants prevailed in 73 percent of the cases (22 out of 30) and brand-name companies prevailed in 27 percent (8 out of 30). Of the decisions favoring the first or any subsequent generic applicant, there were slightly more non-infringement decisions (14) than patent invalidity decisions (11). The U.S. Court of Appeals for the Federal Circuit overturned district court decisions of patent invalidity for drug products in this study in only eight percent of cases.

In 62 percent of the cases involving litigation with the first and second generic applicants, brand-name companies initiated patent litigation in just five federal judicial districts – the District of New Jersey, the Southern District of New York, the Southern District of Indiana, the Northern District of Illinois, and the Southern District of Florida.

C. Findings: Orange Book Patent Listing Practices

The 30-month stay provision of the Amendments protects brand-name companies beyond their existing intellectual property rights. It has received increased attention because it can have a significant impact on market entry by generic drugs. Since 1998, two new phenomena appear to be emerging in relation to patent listing practices that affect patent litigation: (1) an increase in the number of patents listed in the Orange Book for "blockbuster" drug products; and (2) the listing of patents after an ANDA has been filed for the particular drug product.

The Commission found that, for drug products with substantial annual net sales, brand-name companies are suing generic applicants over more patents. Since 1998, for five of the eight "blockbuster" drug products for which the brand-name company filed suit against the first generic applicant, the brand-name company alleged infringement of three or more patents. In comparison, in only one of the nine "blockbuster" suits filed before 1998 by a brand-name company against the first generic applicant did the complaint allege infringement of three or more patents.

[63] There were three additional suits that had other resolutions: either the patent expired before completion of the litigation or the brand-name company withdrew the product prior to completion of the litigation.

In the future, patent infringement litigation brought by brand-name companies against generic applicants that have filed ANDAs with Paragraph IV certifications may take longer to resolve. The data suggest that cases involving multiple patents take longer than those involving fewer patents. As of June 1, 2002, for six out of the seven cases that were pending for more than 30 months before a decision from a district court, the brand-name company has alleged infringement of three or more patents.

By the timely listing of additional patents in the Orange Book after a generic applicant has filed its ANDA ("later-issued patents"), brand-name companies can obtain additional 30-month stays of FDA approval of the generic applicant's ANDA. In eight instances, brand-name companies have listed later-issued patents in the Orange Book after an ANDA has been filed for the drug product. For those eight drug products, the additional delay of FDA approval (beyond the first 30 months) ranged from four to 40 months. In the five cases so far with a court decision on the validity or infringement of a later-issued patent, the patent has been found either invalid or not infringed by the ANDA.[64]

Moreover, several of the later-issued patents in the Orange Book raise questions about whether the FDA's patent listing requirements have been met. For example, several of the later-issued patents do not appear to claim the approved drug product or an approved use of the drug. The FTC Study describes three categories of patents that raise significant listability questions – *i.e.*, issues concerning whether the listed patents fall within the statutorily defined class. These categories include: (1) patents that may not be considered to claim the drug formulation or method of use approved through the NDA; (2) product-by-process patents that claim a known drug product produced by a novel process; and (3) patents that may constitute double-patenting because they claim subject matter that is obvious in view of the claims of another patent obtained by the same person.

D. Recommendations: The 30-Month Stay Provision

To reduce the possibility of abuse of the 30-month stay provision, the Commission recommended in its study that only one 30-month stay be permitted per drug product per ANDA to resolve infringement disputes over patents listed in the Orange Book prior to the filing date of the generic applicant's ANDA. This should eliminate most of the potential for improper Orange Book listings to generate unwarranted 30-month stays. One 30-month stay period alone has historically approximated the time necessary for FDA review and approval of the generic applicant's ANDA[65] or a district court decision on the patent infringement litigation that caused

[64] This number includes one drug product (Paxil) for which the generic applicant has challenged multiple patents. The district courts hearing the patent infringement suits have ruled so far that many of the relevant claims of three patents are invalid and that one patent is not infringed by the generic applicant's ANDA. There has not yet been a ruling on the other patents and ANDA applicants involved in the case.

[65] FDA approval of ANDAs submitted by first generic applicants who were not sued by the brand-name company took, on average, 25.5 months from the ANDA filing date.

the 30-month stay. Moreover, generic applicants generally have not entered the market until a district court has held that the brand-name company's patent was invalid or not infringed.[66] Thus, it does not appear that, on average, one 30-month stay provision per drug product per ANDA would have a significant potential to delay generic entry beyond the time already necessary for FDA approval of the generic applicant's ANDA or a district court decision in the relevant litigation.

Limiting brand-name drug companies to one 30-month stay per drug product per ANDA is likely to eliminate most problems related to potentially improper Orange Book listings. Nonetheless, the Commission notes that there is no private right of action to challenge an improper listing, nor does the FDA review the propriety of patent listings.[67] The lack of a mechanism to review or delist patents may have real-world consequences. For example, the Commission is aware of at least a few instances in which the first 30-month stay was generated solely by a patent that raised legitimate listability questions. One proposal to deal with this problem has been to establish an administrative procedure through which generic applicants could obtain substantive FDA review of listability. The FTC Study recommends, at a minimum, that it would be useful for the FDA to clarify its listing requirements as the Commission suggests.[68] Another remedy that may warrant consideration would be to permit a generic applicant to raise listability issues as a counterclaim in the context of patent infringement litigation that the brand-name company already initiated in response to a Paragraph IV notice from the generic applicant. A challenge limited to a counterclaim would avoid generating additional litigation.

One minor change to the patent statute, which would clarify when brand-name companies can sue generic applicants for patent infringement and allow for the resolution of patent issues prior to commercial marketing of a generic drug, would ensure that brand-name companies have recourse to the courts to protect their intellectual property rights in later-issued patents. To do

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[66] The only instances in which a generic applicant has entered the market prior to a district court resolving the patent infringement litigation has been when the litigation involved a patent that was listed in the Orange Book *after* the generic applicant had filed its ANDA.

[67] *See supra* note 39 and accompanying text. Although the FDC Act does not create a private right of action that would permit a generic drug manufacturer to bring a suit to de-list a patent in the first instance, or to seek de-listing via a counterclaim, the Federal Circuit has held that a district court may order de-listing as a remedy when, in the course of patent infringement litigation, a listed patent is held to be invalid or unenforceable. *Abbott Laboratories v. Novopharm Ltd.*, 104 F.3d 1305, 1309 (Fed. Cir. 1997); *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323, 1333 (Fed. Cir. 2001). *See also* Memorandum of Law of Federal Trade Commission as *Amicus Curiae* Concerning Torpharm's Cross Motion for Entry of an Amended Order, *supra* note 37.

[68] Last week, the FDA issued a final rule amending its regulations governing the availability of, and triggers for, the 30-month stay provisions and to clarify its patent listing requirements. *See supra* note 8. This rule is discussed in Section G *infra*.

this, the FTC Study suggested that Congress may wish to clarify that Section 271(e)(2) of the Patent Act permits a brand-name company to sue a generic applicant for patent infringement regarding patents not listed in the Orange Book.[69]

E. Findings: Patent Settlements and the 180-Day Marketing Exclusivity

Certain patent settlement agreements between brand-name companies and potential generic competitors have received antitrust scrutiny in recent years because not only might they affect when the generic applicant may begin commercial marketing, but they also may affect when the FDA can approve subsequent generic applicants after the first generic applicant's 180-day exclusivity runs. Parties have debated whether these settlements increased or harmed consumer welfare. Twenty final[70] and four interim[71] agreements that settled litigation between the brand-name company and the first generic applicant were produced in response to the FTC's special orders.

The final patent settlements can be classified into three categories:

(1) Nine of these settlements contained a provision by which the brand-name company, as one part of the settlement, paid the generic applicant (settlements involving "brand payments");

(2) Seven of the 20 settlements involved the brand-name company licensing the generic applicant to use the patents for the brand-name drug product prior to patent expiration; and

(3) Two of the settlements allowed the generic applicant to market the brand-name drug product as a generic product, under the brand-name company's NDA but not under not the generic applicant's own ANDA.[72]

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[69] The Federal Circuit's recent decision in *Allergan* may implicate whether a patentee can sue under Section 271(e)(2) of the Patent Act for patents covering unapproved uses of the drug. S*ee Allergan, Inc. v. Alcon Labs,* Docket No. 02-1449 (Fed. Cir. Mar. 28, 2003). We recommended that the analysis of whether an infringement suit is appropriate is distinct from the analysis of whether a patent is appropriately listed in the Orange Book and, therefore, a potential basis for a 30-month stay.

[70] One of these agreements is subject to litigation currently pending at the FTC. *See Schering-Plough Corp.*, Dkt. No. 9297 (complaint issued Mar. 30 2001).

[71] For three out of the four interim agreements, *see Abbott Laboratories*, Dkt. No. C-3945 (May 22, 2000) (consent order) (relating to two drug products, Hytrin tablets and Hytrin capsules); *Geneva Pharmaceuticals, Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order); and *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), all *supra* note 34.

[72] The remaining two settlements do not fit into any of these three categories.

Fourteen of the final settlements with the first generic applicant had the potential to "park" the 180-day marketing exclusivity for some period of time such that the first generic applicant would not trigger the exclusivity, and thus FDA approval of any subsequent eligible generic applicant would be delayed. (If the 180-day exclusivity for the first generic applicant does not run, the FDA cannot approve subsequent eligible generic applicants.) The data from the FTC Study suggest, however, that the 180-day exclusivity provision by itself generally has not created a bottleneck to prevent FDA approval of subsequent eligible generic applicants.

In addition to the final settlements with the first generic applicant, brand-name companies entered final patent settlements with the second generic applicant in seven instances. In six of the seven, the brand-name company also had settled with the first generic applicant.

F. Recommendations: The 180-Day Exclusivity Provision

To mitigate the possibility of abuse of the 180-day exclusivity provision, the FTC Study recommended that Congress pass the Drug Competition Act[73] to require brand-name companies and first generic applicants to provide copies of certain agreements to the Federal Trade Commission and the Department of Justice. The Commission believes that review of these agreements by these agencies will help ensure that the 180-day provision is not manipulated in a way to delay entry of additional generic applicants. Indeed, the Senate did pass the Drug Competition Act last year and the Commission urges passage of the Act again this year.

Empirical research demonstrates that as additional generic competitors enter the market, generic prices decrease to lower levels, thus benefitting consumers. The FTC Study makes three minor recommendations to ensure that, once a subsequent generic applicant is ready to market, the 180-day exclusivity is not a roadblock to that entrant's beginning commercial marketing. Under the second and third recommendations, we note that the first generic applicant does not lose the 180-day period, but rather it is triggered by one of two events. During this 180-day period, the first generic applicant can then decide whether to enter the market prior to a subsequent applicant entering after the 180-day period has expired.

Recommendation 1: To clarify that "commercial marketing" includes the first generic applicant's marketing of the brand-name product.

The data revealed two instances when the brand-name company and the first generic applicant settled the patent infringement lawsuit with a supply agreement. These agreements contemplated that the brand-name company would supply the generic applicant with the brand-name drug product, so that the generic applicant could market the brand-name product as a generic version, rather than seeking approval of its ANDA. To avoid the situation in which the running of the 180 days is not triggered and, thus, forestalling a second generic from obtaining FDA approval, the Commission recommended this type of marketing be deemed sufficient to trigger the 180-day exclusivity period.

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[73] S. 754, 107th Cong. (2001) (introduced by Sen. Leahy).

Recommendation 2: To clarify that the decision of any court on the same patent being litigated by the first generic applicant constitutes a "court decision" sufficient to start the running of the 180-day exclusivity.

There is some question about *which* court's decision is sufficient to activate the "court decision" trigger of the 180-day exclusivity. Two courts of appeal have held,[74] and the FDA has issued guidance,[75] that *any* court's decision on whether the patent at issue is invalid or not infringed is sufficient to trigger the running of the first generic applicant's 180-day exclusivity.

On balance, the Commission believes that this is the correct result, but there are pros and cons. On the one hand, the rule would make it less likely that agreements between brand-name and generic companies that had the effect of "parking" the 180-day exclusivity for some period of time could forestall FDA approval of a subsequent eligible generic applicant. If the brand-name company sues the second (or later) generic applicant, and that generic applicant won its patent litigation, then the 180-day exclusivity of the first generic applicant would begin to run from the date of the later generic applicant's favorable court decision. Such circumstances may arise; the data showed that brand-name companies sued later generic applicants in nearly 85% of the cases. The rule would be consistent with the mandate in the legislative history of Hatch-Waxman to "make available more low-cost drugs,"[76] because the rule would assist in eliminating potential bottlenecks to FDA approval of subsequent eligible generic applicants.

Such a rule also could speed generic entry when the second generic applicant's lawsuit is resolved prior to that of the first applicant. This appears to be appropriate given the low reversal rate of district court opinions of patent invalidity and non-infringement. For example, under this rule, if both the first and second generic applicants are sued, but the court hearing the second generic applicant's case is the first to arrive at a decision, then that court's decision would trigger the running of the first generic applicant's 180-day exclusivity, regardless of whether the first generic applicant had received FDA approval. The data revealed one such case.

On the other hand, the operation of this rule could deprive the first generic applicant of its ability to market under the 180-days exclusivity if the district court hearing its suit had not yet ruled, even though the first generic applicant had been diligently pursuing resolution of its patent

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[74] *See Teva Pharmaceuticals, USA, Inc. v. FDA*, 182 F.3d 1003 (D. C. Cir 1999); *Granutec, Inc. v. Shalala*, 139 F.3d 889 (4th Cir. 1998).

[75] *See* FDA Guidance for Industry: 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act (Jun. 1998). *See also Teva Pharmaceuticals, USA, Inv. v. FDA*, 182 F.3d 1003, 1005 (D.C. Cir. 1999).

[76] H.R. Rep. No. 98-857, pt. 1, 98th Cong., 2d Sess., at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

litigation. This result could dampen the incentive to become the first generic applicant.[77] Moreover, if the later court issues a non-infringement decision, the reasoning underlying the holding may not apply to the first generic applicant's ANDA, depending upon the facts of the case.

Recommendation 3: Clarify that a court decision dismissing a declaratory judgment action for lack of subject matter jurisdiction constitutes a "court decision" sufficient to trigger the 180-day exclusivity.

One court of appeals has held that a dismissal of a declaratory judgment action for lack of a case or controversy is a "court decision" of non-infringement sufficient to trigger the 180-day exclusivity.[78] In the FTC Study, the Commission found the court's reasoning persuasive, and recommended that Congress adopt such a rule.

The U.S. Court of Appeals for the District of Columbia confronted a situation in which the brand-name company did not sue any of the generic applicants for patent infringement. To trigger the first generic applicant's 180-day exclusivity (because it had not yet been approved by the FDA), the second generic applicant sought a declaratory judgment that its ANDA did not infringe the brand-name product's patents. The district court hearing the case dismissed the lawsuit for lack of subject matter jurisdiction, because the brand-name company indicated that it would not sue the second generic applicant for patent infringement, thus eliminating its reasonable apprehension of a patent infringement suit and the existence of a case or controversy. This dismissal also estopped the brand-name company from suing the generic applicant in the future.

The Court of Appeals determined that the dismissal for lack of case or controversy was, in fact, a court decision, because the brand-name company indicated that the second generic applicant's ANDA did not infringe the relevant patent. As a result, the dismissal activated the court decision trigger. Such a rule eliminates the potential for a bottleneck created if a first generic applicant does not exercise its commercial marketing rights.

G. The FDA's New Rules on the 30-Month Stay and Orange Book Listings

Last week the FDA published final rules amending its regulations governing patent listing in the Orange Book and eligibility for the 30-month stay of ANDA approval.[79] The FDA

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[77] By contrast, the absence of such a rule also could dampen the incentive for later generic applicants to develop eligible ANDAs containing paragraph IV certifications.

[78] *Teva Pharmaceuticals, USA, Inc. v. FDA*, 182 F.3d 1003 (D. C. Cir 1999).

[79] Department of Health and Human Services, Food and Drug Administration, Applications for FDA Approval to Market a New Drug; Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed, Final Rule (June 12, 2003).

had proposed this rule last year, in part, based on the competitive problems with the current generic drug approval process the Commission identified in the FTC Study.

The final rule limits brand-name companies to one 30-month stay per drug product. Although this rule is not identical to the FTC Study's recommendation, it is an important reform that would eliminate most of the potential for unwarranted delay of FDA approval of generic drugs the FTC Study identified. In particular, the rule, if upheld against legal challenge, would eliminate seven of the eight instances the Commission identified in the Study in which brand-name companies filed patents in the Orange Book after a generic applicant had filed an ANDA application and, thus, delayed FDA approval of the ANDA for an additional 30 months. The final rule does not cover those situations in which the generic applicant has filed an ANDA with a paragraph III certification on a particular patent and seeks FDA approval after the expiration of that patent. If on the eve of that patent's expiration, the brand-name company files a new patent in the Orange Book, there is a potential for a 30-month stay to be granted. This is the situation for the drug product Platinol (the eighth of the eight drug products the FTC Study identified with multiple 30-month stays).

The final rule also tightens up the Orange Book patent listing requirements. The FTC Study had identified several types of patents that raise questions about whether they are properly listed in the Orange Book, and which can form the basis for a 30-month stay. The final FDA rule prohibits the listing of two of these types of patents (metabolites and product-by-process), and requires additional information from the brand name company if it seeks to list in the Orange Book the third type of patent (polymorphs) identified by the Study.

V. Conclusion

Thank you for this opportunity to share the Commission's views on competition in the pharmaceutical industry. As you can see, the Commission has been and will continue to be very active in protecting consumers from anticompetitive practices that inflate drug prices. The Commission looks forward to working closely with the Committee, as it has in the past, to ensure that competition in this critical sector of the economy remains vigorous. In keeping with this objective, the Commission will likewise endeavor to ensure that the careful Hatch-Waxman balance – between promoting innovation and speeding generic entry – is scrupulously maintained.

UNITED STATES SENATOR • IOWA
CHUCK GRASSLEY

http://grassley.senate.gov
grassley_press@grassley.senate.gov

Contact: Jill Kozeny, 202/224-1308
Beth Pellett, 202/224-6197
Dustin Vande Hoef, 202/224-0484

Statement of Sen. Chuck Grassley, of Iowa
Senate Committee on the Judiciary Hearing
The FTC Study on Barriers to Entry in the Pharmaceutical Marketplace
Tuesday, June 16, 2003

Mr. Chairman, thank you for scheduling this important hearing. We want to ensure that all Americans, especially seniors, have access to the life-saving prescription drugs they need in the most timely manner possible. The FTC plays an important role in making sure that competition is fair and open, and that consumers are not hurt by anti-competitive behavior.

I'd like to say a few words about the FTC report and the Drug Competition Act of 2003. The study that the FTC recently completed looking at competition in the prescription drug area has brought to light problems that I believe can be addressed by Congress.

The Hatch-Waxman law was designed to create a balance in the prescription drug market. This law gives drug companies an incentive to develop and research new drug opportunities, while at the same time ensures that generic drug companies can introduce prescription drugs into the market in a timely fashion so that there is competition. Maintaining a balance that facilitates competition translates into lower prices for consumers.

However, some companies have disrupted this careful balance by entering into secret agreements with the brand name companies. In these instances, the brand name drug companies have paid generic companies not to release their product into the market as soon as possible, in such a way as to not trigger the start of the 180-day grace period required under the Hatch-Waxman law. This has resulted in prices remaining high for certain drugs because other companies are prevented from competing with their products.

In the report, the FTC indicated that the Drug Competition Act, introduced by Senator Leahy, would help ensure that these companies not enter into these anti-competitive agreements. I'm a co-sponsor of the Drug Competition Act, which is designed to end the exploitation of the 180-day period of exclusivity, and to make sure that consumers can benefit from lower priced drugs.

Under this bill, if prescription drug companies enter into agreements concerning the 180-day period, they must file those documents with both the FTC and the Department of Justice. If documentation is not filed within a certain timeframe, then the companies will be subject to sanctions. I think that this is a modest step that can do much in terms of ensuring that companies are contracting in a way that complies with the spirit of the law and that does not hurt consumers.

Congress should do all that it can to promote the development of new and more effective prescription drugs. It is just as important that Congress do everything in its power to facilitate competition in the marketplace, and to make prescription drugs affordable for all Americans.

Hearing Before the Committee on the Judiciary
United States Senate
On
"Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace"

June 17, 2003

Testimony of Kathleen D. Jaeger, R.Ph., J.D.

President & CEO

2300 Clarendon Blvd., Suite 400
Arlington, VA 22201
703-647-2480/f. 703-647-2481

I. Introduction

Mr. Chairman. Distinguished Members of the Committee. My name is Kathleen Jaeger, and I am the President and CEO of the Generic Pharmaceutical Association. I am also a pharmacist, and an attorney, who specializes in FDA-regulatory law; and a long-time consumer and industry advocate. As a pharmacist and coming from a family-owned pharmacy background, I understand the need consumers have for choice, and the challenge of placing affordable medicine in their hands.

On behalf of GPHA and its more than 140 members, I especially want to thank you, Mr. Chairman, for convening this hearing to discuss the FTC Report, the FDA Rule, and the legislation sponsored by Senators Gregg, Kennedy, McCain and Schumer, and supported by the President, which would increase consumer access and close existing loopholes in the approval of affordable prescription drugs. We appreciate your leadership on this issue, both on the original Hatch-Waxman Act nearly 20 years ago, and today.

We applaud the President and the Senators for their commitment to a package of administrative and legislative measures that — if taken together and not weakened — will ensure that American health care becomes more affordable. As you know, S. 1225, the Greater Access to Affordable Pharmaceuticals Act, was unanimously passed by the Senate Health, education, Labor and Pensions Committee last week. And we echo the President's intention to "work with both the House and the Senate on this legislation to make certain that prescription drugs are more affordable to the American people."

GPHA represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. GPHA members manufacture more than 90% of all generic drug doses dispensed in the United States. Our products are used in more than one billion prescriptions every year. We are a significant segment of America's pharmaceutical industrial sector, providing affordable drug therapies to treat millions of American patients daily.

As President Bush said in remarks June 11, 2003, "the challenge for America is to make sure that life-saving drugs are both affordable and available to America's seniors." He noted that "one way to make prescriptions more affordable is to ensure that generic drugs are not delayed in reaching the market, are not delayed for consumers to be able to purchase."

To that end, President Bush announced several measures to ensure consumers have timely access to affordable prescription drugs, including complementary new FDA regulations. While we commend the President's initiative, it is clear to GPhA that due to statutory limitations on the Administration's authority, the FDA rule does not sufficiently effectuate the President's desire to

"close the loopholes, to promote fair competition and to reduce the cost of prescription drugs in America." That is why we are testifying here today.

We believe that the Gregg-Schumer bill will remove some of the most serious market barriers to generic competition, while simultaneously lowering costs and preserving the incentives that promote new product discovery and innovation. The compromise legislation recognizes that the blend of brand and generic pharmaceuticals allows Americans to live healthier, more productive lives. GPhA strongly believes that the Administration's complementary regulatory initiatives, coupled with substantial legislative measures in the compromise legislation, will ensure that American health care becomes more affordable.

II. Generic Drugs Create Savings for America's Health Care System

Health care providers, purchasers, and consumers have come to recognize and depend upon the enormous therapeutic and economic value affordable pharmaceuticals offer the nation's health care system. These diverse groups understand that generic pharmaceuticals provide the same quality of medical care as their brand counterparts, while also providing the financial headroom to accommodate other health care modalities, such as innovative lifesaving treatments.

Generics are used to fill one of every two prescriptions. Yet, generics account for less than eight cents of every dollar consumers and providers spent on prescription pharmaceuticals last year. Moreover, an increase in generic prescription utilization by merely one percent would generate additional savings of $1 billion dollars or more across this nation. Given these facts, it is unquestionably clear that consumers should have timely access to affordable generics and that generics should be fully integrated into current and future health care programs. The measures included in the FDA rule, coupled with the emerging compromise legislation, could have a profound impact on the economic and therapeutic health of Americans.

For instance, potential savings over a 10-year period generated by the use of generics in Medicare alone could be more than $250 billion. Generic utilization can provide a solid platform for a prescription drug benefit program under which new, lifesaving drugs or other medical interventions become more affordable. Simply put, savings derived from such a generic platform benefit not only the program at issue, but the entire American health care system.

Congressional action to close the unintended loopholes in current law would benefit private and public entities as well as the uninsured and insured alike. Detractors of such initiatives suggest that reform would come at the expense of intellectual property and would therefore diminish the hope of Americans suffering from life-threatening illnesses. In fact, the opposite is true.

The best way to promote innovation, to provide an incentive to develop the next, medical breakthrough product, is to foster competition. Allowing a brand product to have unlimited monopoly protection distorts the incentive, and results in the adoption of a brand preservation strategy, rather than an innovation strategy. A number of organizations have explored the issue of generic competition and brand pharmaceutical innovation over the past several years, in an effort to confirm the contention of the brand pharmaceutical industry that the "search for cures"

is at risk. The results of these separate analyses are consistent. Competition is good for innovation, and the brand pharmaceutical industry has thrived since 1984.

Hatch-Waxman recognized that brand companies need and deserve a period of market exclusivity to recoup their investment in research and development. It established a specific period of exclusivity, and then permitted the date-certain introduction of more affordable generic versions of these brand drugs. But no generic drug can be approved, or enter the market as long as a patent protects the brand product. Modest reform of Hatch-Waxman does not change this fact. Rather, it ensures that patents expire when Congress intended. It closes loopholes that in essence create an indefinite period of exclusivity. It ensures that patents come to an end, and that generic products can enter the market when the patents expire.

Taken together, it is the blend of pharmaceuticals — brand and generic — that keep Americans productive and healthy, and able to avoid other, more expensive medical and surgical interventions. That is why many private and public entities view generics as part of the solution to the complex health care challenges of the 21st century.

For example, his year alone, blockbuster drugs with sales of nearly $6 billion are expected to come off patent, enabling generic competition that will create savings of as much as 80 percent. But loopholes in Hatch/Waxman, if not closed in a timely manner, could delay this savings.

If Congress had been successful in approving S. 812 last session, Americans would already be on its way to saving a minimum of *$60 billion over the next ten years*. The reasons that supported approval of S. 812 last year are, if anything, even more critical today. The federal government is reeling under the weight of escalating prescription drug costs. States across the nation are reeling under the weight of out of control health care bills. Large employers and health care plans face unsustainable costs, and American consumers, particularly seniors, continue to seek relief.

Last fall, AARP released the results of a poll that confirm what we have been saying in testimony before the Senate – and what every lawmaker already knows: the high cost of prescription drugs is a critical problem facing American consumers. In a mid-September 2002 telephone survey of 1,046 people 45 years of age or older, AARP found that:

- 84% of older Americans strongly believe that making generic drugs more available is an important part of the solution to rapidly increasing drug prices. 62% feel very strongly about this.

- 90% of Americans say they are willing to take generic drugs to reduce their costs.

- 92% of Americans are concerned about the impact of rising drug prices on the ability of insurance plans and employers to provide affordable healthcare coverage.

- 80% of Americans want action now. They want Congress to take immediate action to lower prescription drug costs.

- More than two-thirds support legislation, like GAAP, that would close loopholes that prevent timely introduction of generic drugs.

Nearly one year later, American consumers are still paying too much for some prescription drugs, and not able to get access to generic versions of others, because the loopholes that prevent timely access to generic versions of some brand name drugs remain open.

III. The FTC Report Found that Loopholes Delay Generic Competition

The Federal Trade Commission, in its July 2002 Report, "Generic Drug Entry Prior to Patent Expiration," concluded that certain provisions of Hatch-Waxman "are susceptible to strategies that ... may have prevented the availability of more generic drugs." The FTC further warned that, "These provisions continue to have the potential for abuse."

As the Report explained, when a generic applicant challenges the patents that prevent consumer savings, and are subsequently sued by the brand name drug company, there is an automatic "30-month stay" that prevents FDA approval of the generic product. The Report noted that multiple 30-month stays are "problematic" and FTC recommended limiting brand companies to one 30-month stay. The study concluded that "stacking" of 30-month stays has delayed generic approval for 4 to 40 months beyond the first 30-month stay. FTC concluded that brand companies began using the "stacking" tactic around 1998 and that the number of listed patents per blockbuster drug has increased significantly since that time. FTC correctly observed that, like any patent owner, brand companies can prevent generic marketing by demonstrating entitlement to a preliminary injunction and further concluded that were no instances where a generic drug entered the market and was later found to be infringing on the brand's patent.

In regard to patent challenges, the study data reveal that generics win 73 percent of the patent litigation. FTC concluded that generics are bringing "appropriate challenges" to brand patents. The FTC Report also found that improper patent listings are a continuing problem for which the current system provides no remedy. FTC cited numerous examples of listed patents that clearly do not claim the approved drug or an approved use of the drug, such as Fosamax, Neurontin, and Tiazac. It further concluded that the failure to police the patent listing process combined with multiple 30-month stays presents "real world consequences" for consumers.

Thus, the FTC Report is entirely consistent with efforts to limit the 30-month stay, enforce the patent listing requirements, and restore the value of the patent challenge incentive.

Also last year, the Congressional Budget Office reported in a study that American consumers will save $60 billion dollars over the next 10 years, if Congress enacted S. 812. CBO's analysis concluding that fair competition in the prescription drug market is pro-consumer and pro-

savings, supports the need for modest Hatch-Waxman reform. Moreover, these savings will make a prescription drug benefit more affordable.

IV. The Gregg-Schumer Legislation Provides Timely Access to Affordable Prescription Drugs

The Gregg-Schumer bill achieves significant savings by removing the most serious barriers to generic competition. I would like to address several key provisions of the compromise bill.

A. Preventing "Eleventh-Hour" Gaming of the System

Gregg-Schumer limits brand companies to only one "30-month stay" of generic drug approval in the event of a patent challenge. The single 30-month stay is available only on patents that were published in the FDA Orange Book at least 1 day before a generic application is filed. This represents a significant compromise from S.812 that would have permitted stays only on patents listed at the time the brand drug was approved. Thus, the compromise will give brand companies significantly more time to obtain and list patents that will trigger the single, automatic 30-month stay that blocks generic competition.

B. Provision to Provide Timely Resolution of Patent Disputes

The ability to receive a 30-month stay for new patents is the incentive for brand companies to bring their lawsuits within 45 days. Without the possibility for a second 30-month stay, brand companies could stall generic competition by waiting until the eve of the generic approval before bringing an infringement lawsuit.

The FDA states in the preamble to its rule that generic applicants can "resolve their concerns about commencing litigation quickly by providing voluntary notice to the NDA holder and patent owner as they wish." However, GPhA believes that without explicit statutory provision to allow generic companies to quickly resolve patent disputes, American consumers will not enjoy improved access to affordable prescription drugs.

Gregg-Schumer provides a necessary, pro-consumer check and balance to the single 30-month stay provision by permitting a generic applicant to bring a declaratory judgment action if the patent holder does not sue within 45 days of notification of a generic application.

(1) Constitutionality

Some have alleged that the declaratory judgment provision of the emerging compromise bill may raise issues of constitutionality. GPhA strongly believes that such allegations are without merit. GPhA has consulted with several experts in constitutional law, including John Yoo. Mr. Yoo served as General Counsel to this Committee under Chairman Hatch from 1995-96. In addition, Mr. Yoo has clerked for Justice Clarence Thomas of the U.S. Supreme Court and currently is a visiting fellow at the American Enterprise Institute and a professor of law at Boalt Hall School of Law, University of California at Berkeley. Mr. Yoo's analysis follows:

June 14, 2003

The Honorable Orrin G. Hatch
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20001

Dear Senator Hatch:

I have been asked by the Generic Pharmaceutical Association to provide my views concerning the constitutionality of a proposed amendment to the Hatch-Waxman Act. The amendment would allow a generic drug manufacturer who has filed an abbreviated new drug application (ANDA) to seek federal declaratory relief against potential patent infringement claims. It is my opinion that this provision is clearly constitutional.

Let me begin with a note of introduction. I have long worked on separation of powers issues involving the courts.[1] It was my great honor to have served as the General Counsel to this Committee under your Chairmanship from 1995-96. I also recently served as Deputy Assistant Attorney General in the Office of Legal Counsel of the Department of Justice, which is charged in part with advising the executive branch on the constitutionality of proposed legislation. I have clerked for Judge Laurence Silberman of the U.S. Court of Appeals for the D.C. Circuit and for Justice Clarence Thomas of the U.S. Supreme Court. I am currently a visiting fellow at the American Enterprise Institute and a professor of law at the Boalt Hall School of Law, University of California at Berkeley, where I have taught and written in the fields of constitutional law, the separation of powers, and civil procedure since 1993. The conclusions expressed here are my own, and do not represent the views of the American Enterprise Institute or the University of California.

In order to evaluate the constitutionality of the proposed changes, it is necessary to first understand the statutory framework at issue. Under the Federal Food, Drug, and Cosmetic Act, a pharmaceutical company that seeks to manufacture a new drug must file a new drug application (NDA) with the FDA that includes information about the drug's safety and effectiveness. 21 U.S.C. §355(a). The NDA must also include a list of patents upon which the drug is based. If the FDA approves the NDA, it publishes the drug and the patents in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

The Hatch-Waxman amendments created a streamlined process for the FDA to review applications by drug manufacturers to produce generic versions of drugs previously approved by the NDA process. Under an ANDA, a generic producer may rely in part on the NDA of the

[1] *See, e.g.*, John Yoo, *Who Measures the Chancellor's Foot?: The Inherent Remedial Powers of the Federal Courts*, 84 Cal. L. Rev. 1121-1177 (1996); John Yoo, *The Judicial Safeguards of Federalism*, 70 S. Cal. L. Rev. 1311-1405 (1997); John Yoo, *The Origins of Judicial Review*, 70 U. Chi. L. Rev. (forthcoming 2003) (with Sai Prakash).

pioneer manufacturer by showing bioequivalence with the NDA-approved drug. 21 U.S.C. §355(j)(2)(A). Under Hatch-Waxman, it is not patent infringement to conduct actions necessary to prepare an ANDA, 35 U.S.C. §271(e)(1), but it is infringement to file the ANDA itself before the expiration of the patents that include the pioneer drug, *id.* §271(e)(2). An ANDA applicant must make one of four certifications as to the patents listed in the Orange Book for the pioneer drug it seeks to manufacture: i) no patent information has been submitted to the FDA; ii) the patent has expired; iii) the patent will expire on a specific date; iv) the patent is invalid and will not be infringed by the generic drug.

When an ANDA makes the fourth certification, known as a Paragraph IV certification, the applicant must give notice to the patent holder and explain why the patent is invalid, unenforceable, or not infringed. 21 U.S.C. §355(j)(2)(B)(i). The patent holder may sue for infringement within the next 45 days, *id.* §355(j)(5)(B)(iii), and if it does, the FDA may not approve the ANDA application until the courts have ruled on the suit, the relevant patents have expired, or thirty months have passed from the time of the original notice. *Id.* During that 45-day period, "no action may be brought under section 2201 of Title 28 [the Declaratory Judgment Act], for a declaratory judgment with respect to the patent." *Id.*[2]

The proposal before you would make clear what this last provision already implies. It would recognize that "an actual controversy" between an ANDA filer and a patent holder would exist "sufficient to confer subject matter jurisdiction in the courts of the United States" if, after 45 days have passed since the ANDA has been filed, the patent holder chooses not to bring a patent infringement action. I do not believe that this provision poses constitutional problems; in fact, it merely clarifies the proper application of existing law.

To understand why, it is necessary to review the Declaratory Judgment Act and its interaction with patents. Article III, Section 2 of the Constitution allows federal courts to exercise jurisdiction only over the enumerated list of cases or controversies. U.S. Const. art. III, § 2 (listing cases or controversies). As *Marbury v. Madison* made clear, federal courts are courts of limited subject matter jurisdiction. For many years, it was uncertain whether declaratory judgment actions fell within the definition of an Article III case or controversy. Federal jurisdiction certainly extends to cases in which a plaintiff is entitled to a coercive remedy based on federal law. Substantial hardship arises, however, in cases involving "an actual dispute about the rights and obligations of the parties, and yet the controversy may not have ripened to a point at which an affirmative remedy is needed. Conversely, this stage may have been reached, but the party entitled to seek the remedy may fail to take the necessary steps." C. Wright & A. Miller, Federal Practice and Procedure § 2751. In the area of patents, "the owner of a patent might

[2] The U.S. Court of Appeals for the Federal Circuit has found that a generic drug producer could not bring such a claim because a patent holder had failed to follow proper procedures in listing a patent in the Orange Book. *Mylan Pharmaceuticals v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), cert. denied 123 S. Ct. 340 (2002). The Federal Circuit, however, rejected the declaratory action because the plaintiff had not claimed the patent to be invalid, unenforceable, or not infringed, as specified by Paragraph IV, but rather had sought a private cause of action to de-list the patent itself. *Id.* at 1332. In a subsequent case, the Federal Circuit has found that improper listing in the Orange Book must be challenged under the Administrative Procedure Act. *See Andrx Pharmaceuticals v. Biovail Corp.*, 276 F.3d 1368 (Fed Cir. 2002).

assert that a manufacturer was infringing the owner's monopoly, while the latter contended that his product was not an infringement or that the patent was invalid. The manufacturer was helpless, however, to secure an adjudication of the issue, but had to await suit for infringement, unless the manufacturer preferred to yield and discontinue the activity." *Id.*

Declaratory judgments acts first arose in the states, but uncertainty initially remained as to whether such cases could be heard in federal courts due to the case or controversy requirements of Article III of the Constitution. *Willing v. Chicago Auditorium Ass'n*, 277 U.S. 274 (1928). In 1927, however, the Court gave res judicata effect to a state declaratory judgment, *Fidelity Nat'l Bank & Trust Co. v. Swope*, 274 U.S. 123 (1927), and in 1933 it upheld a state court declaratory judgment, *Nasville, C. & St. L. Ry. v. Wallace*, 288 U.S. 249 (1933). Immediately after *Wallace*, Congress enacted the Declaratory Judgment Act:

> In a case of actual controversy within its jurisdiction, ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

Act of June 14, 1934, ch. 512, 48 Stat. 955, codified at 28 U.S.C. §2201(a). In essence, this act allows plaintiffs to bring suit against a defendant who would hold a federal right to seek a coercive remedy against the plaintiff, if the defendant had chosen to bring suit first. The legislative history of the Act reflects that Congress was concerned about the uncertainty in business and legal relations, including the case in which a patent holder chose to delay litigation for patent infringement.[3]

The Supreme Court soon made clear that the Declaratory Judgment Act was constitutional, even though the statute extended federal jurisdiction to cases in which the holder of the federal right had not yet sought to enforce his federal right. Finding that declaratory judgment suits met Article III's case or controversy requirement, the Court explained:

> The Declaratory Judgment Act of 1934, in its limitation to "cases of actual controversy," manifestly has regard to the constitutional provision and is operative only in respect to controversies which are such in the constitutional sense. The word "actual" is one of

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[3] *See* L. Dolak, *Declaratory Judgment Jurisdiction in Patent Cases: Restoring the Balance Between the Patentee and the Accused Infringer*, 38 B.C. L. Rev. 903, 910 (1997). Indeed, Professor Edson R. Sunderland, an advocate of the Act, testified before Congress that:

> I assert that I have a right to use a certain patent. You claim that you have a patent. What am I going to do about it? There is no way that I can litigate my right, which I claim, to use that device, except by going ahead and using it, and you [the patent holder] can sit back as long as you please and let me run up just as high a bill of damages as you wish to have me run up, and then you may sue me for the damages, and I am ruined, having acted all the time in good faith and on my best judgment, but having no way in the world to find out whether I had a right to use that device or not.

Quoted in *id.* at 911. A comprehensive review of the legislative history of the Act may be found Donald L. Doernberg & Michael B. Mushlin, *The Trojan Horse: How the Declaratory Judgment Act Created a Cause of Action and Expanded Federal Jurisdiction While the Supreme Court Wasn't Looking*, 36 UCLA L. REV. 529 (1989).

> emphasis rather than of definition. Thus the operation of the Declaratory Judgment Act is procedural only. In providing remedies and defining procedure in relation to cases and controversies in the constitutional sense the Congress is acting within its delegated power over the jurisdiction of the federal courts which the Congress is authorized to establish. . . . Exercising this control of practice and procedure the Congress is not confined to traditional forms or traditional remedies.

Aetna Life Insurance Company v. Haworth, 300 U.S. 227, 240-41 (1937). In explaining more precisely why the Declaratory Judgment Act did not include cases that were actually unripe or moot, Chief Justice Hughes wrote:

> A "controversy" in this sense must be one that is appropriate for judicial determination. . . . A justiciable controversy is thus distinguished from a difference or dispute of a hypothetical or abstract character; from one that is academic or moot. . . . The controversy must be definite and concrete, touching the legal relations of parties having adverse legal interests. . . . It must be a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts. . . . Where there is such a concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged, the judicial function may be appropriately exercised although the adjudication of the rights of the litigants may not require the award of process or the payment of damages. . . . And as it is not essential to the exercise of the judicial power that an injunction be sought, allegations that irreparable injury is threatened are not required.

Id. at 240-41. In the wake of *Aetna*, the lower courts regularly assumed jurisdiction over declaratory judgment suits by an alleged patent infringer for a declaration of non-infringement or patent invalidity, because the declaratory defendant could have brought a federal action against the declaratory plaintiff. *Edelamnn & Co. v. Triple-A Specialty Co.*, 88 F.2d 852 (7th Cir. 1937). In passing, the Supreme Court has approved this exercise of jurisdiction because a patent infringement suit by the declaratory defendant would have fallen within the Article III "arising under" jurisdiction. *See Franchise Tax Board of California v. Construction Laborers Vacation Trust*, 463 U.S. 1, 20 n. 19 (1983); *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

In light of these cases, it should be clear that Congress intended that potential patent infringers be able to seek a declaration of non-infringement, unenforceability, or invalidity of a patent. Further, the Supreme Court and the lower federal courts have interpreted the Declaratory Judgment Act to allow these suits, and they have also found such suits to fall within Article III's case or controversy requirement. The proposal before you clearly falls within the scope of the Declaratory Judgment Act. A generic drug company wishes to manufacture and sell a substance that mimics a pioneer drug for which patents are listed in the Orange Book. The enforcement of the patent could prevent the generic drug company from producing and selling its product, nullifying its investments in research and production, and potentially subjecting any profits to the uncertainty of a future lawsuit. In filing an ANDA, the generic drug company declares its intention and ability to produce the drug, which renders the dispute anything but hypothetical.

The Hatch-Waxman amendments even find an ANDA filing to constitute patent infringement. Were the pioneer drug company to bring a patent infringement action, the case clearly would fall within Article III's arising under jurisdiction.

It is my view that such actions, as recognized by the proposed amendment before you, would fall within the proper application of the Declaratory Judgment Act and, as interpreted by the Supreme Court and the lower federal courts, within the Constitution's requirements for an actual case or controversy. As the Supreme Court explained in *Aetna*, "[t]he controversy must be definite and concrete, touching the legal relations of parties having adverse legal interests. . . . It must be a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." 300 U.S. at 240-41. Here, there are clear adverse legal interests between the pioneer drug manufacturer and the generic drug manufacturer over the validity and application of a patent. The generic drug manufacturer has invested a substantial amount of resources to file an ANDA and to prepare and manufacture the generic drug; that investment could be lost through a patent infringement action brought by the pioneer drug company. It is difficult to conceive of a setting in which application of the Declaratory Judgment Act would not be more appropriate. Indeed, the proposal before you strikes me as simply a restatement of the proper interpretation of current law.

Some might argue, however, that the proposal could raise constitutional concerns under the case law of the U.S. Court of Appeals for the Federal Circuit. The Federal Circuit has developed a two-part test to determine whether a potential patent infringer's suit lies properly within the Declaratory Judgment Act:

> First, the plaintiff must actually produce or be prepared to produce an allegedly infringing product. Second, the patentee's conduct must have created an objectively reasonable apprehension on the part of the plaintiff that the patentee will initiate suit if the activity in question continues.

EMC Corp. v. Norand Corp., 89 F.3d 807, 811 (Fed. Cir. 1996), *cert. denied*, 117 S. Ct. 789 (1997); *see also Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988). The first prong is easily satisfied in ANDA declaratory judgment actions: by conducting the research and expending the resources necessary to complete an ANDA, the generic drug manufacturer has shown it is prepared to produce the allegedly infringing product. *DuPont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397, 1401 (Fed. Cir. 1995).

Whether an action will meet the Federal Circuit's second prong will depend on the defendant's conduct. One might argue, I suppose, that a pioneer drug producer's refusal to initiate a lawsuit within the 45-day period could be taken as a sign that there is no "objectively reasonable apprehension." This conclusion, however, seems doubtful to me. The Federal Circuit clearly employs a totality of the circumstances approach toward determining "reasonable apprehension," one that looks at conduct that falls far short of simply filing a lawsuit. *See Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 889 (Fed. Cir. 1992). In some cases, the Federal Circuit has looked to the activity of the patent holder in regard to third parties, *Arrowhead*, 846 F.2d at

736-39, express written or oral charges of infringement by the patent holder, *id.* at 736; *Shell Oil Co.*, 970 F.2d at 889, or a threat of a suit, *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993). The proposed amendment would make clear that conduct that falls short of filing a lawsuit is still sufficient to support a declaratory judgment action by a generic drug manufacturer concerned about potential patent infringement.

In any event, even if one were to conclude that the amendment is inconsistent with the Federal Circuit's two-prong test, this would not render the proposal unconstitutional. First, it does not appear to me that the Federal Circuit's approach is required by Article III of the Constitution, nor is it demanded by the Supreme Court's interpretation of the Declaratory Judgment Act. Indeed, the very point of the Declaratory Judgment Act was to allow parties concerned about the uncertainty in their business and legal activities created by the holder of a federal cause of action who refuses to sue. Nothing in the Supreme Court's case law, which has consistently upheld the constitutionality of the Declaratory Judgment Act, has suggested that a declaratory defendant's failure to bring a lawsuit itself within a certain time period eliminates the "actual controversy" required by both the statute and the Constitution. If anything, the case here is the reverse: it is because the declaratory defendant has *not* brought a lawsuit that a plaintiff must seek a federal declaratory action.

In this respect, it may be best to conceive of the Federal Circuit's two-prong test as an exercise of its discretionary powers under the Declaratory Judgment Act, rather than as a true test of Article III justiciability. The Act itself states that a court "*may* declare the rights and other legal relations" of a party. 28 U.S.C. §2201 (emphasis added). The Supreme Court has interpreted this language as allowing the federal courts to decline to adjudicate a federal declaratory action even if case or controversy jurisdiction exists. *Public Serv. Comm'n v. Wycoff Co.*, 344 U.S. 237, 241 (1952); *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286-87 (1995). It seems to me that the Federal Circuit's two-prong approach, which does not derive directly from Article III or the Supreme Court's interpretation of the Declaratory Judgment Act, therefore should be seen as an exercise of the Federal Circuit's discretionary authority. As such, it is clearly subject to Congress's authority to set the rules of procedure that govern the federal courts. Indeed, it is that same power that the Supreme Court found to justify the constitutionality of the Declaratory Judgment Act itself. If Congress wishes to direct the federal courts to adjudicate Declaratory Judgment Act cases in certain circumstances, instead of declining as a matter of prudence to exercise jurisdiction, that is its prerogative. The proposed amendment may be seen as nothing more than an effort to do just that.

Even if the Federal Circuit's two-prong approach were thought to be an interpretation of the Article III case or controversy requirement, that would still not compel a conclusion that the amendment is unconstitutional. The Supreme Court has never passed on the Federal Circuit's "reasonable apprehension" test, and in its earlier cases it has approved more expansive approaches to jurisdiction under the Declaratory Judgment Act. As an independent, coordinate branch of government, Congress has the authority to make its own judgments about the meaning of the Constitution. Congress has the authority to refuse to enact legislation its believes to be unconstitutional, even if the courts think otherwise, and, conversely, it may pass legislation at odds with previous Supreme Court decisions, as it did in the Religious Freedom Restoration Act

at issue in *City of Boerne v. Flores*. To be sure, the Supreme Court has long made clear that Congress does not have the authority to alter the boundaries of the federal judicial power as established in Article III of the Constitution. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992). Nonetheless, Congress's authority to interpret the Constitution, which is fundamental to the separation of powers, certainly must include the ability to reject lower court decisions in order to spark Supreme Court review of whether these courts have properly interpreted Article III of the Constitution. Of course, this may be wholly unnecessary because the Federal Circuit has yet to hold that the absence of a suit during the 45-day period is sufficient *per se* to destroy an actual controversy in a declaratory judgment act by a generic drug manufacturer.

Please do not hesitate to contact me if I can provide further assistance. I may be reached at 202-862-5819, or at yoo@law.berkeley.edu.

Sincerely,

John Yoo
Professor of Law
Boalt Hall School of Law
University of California at Berkeley
Berkeley, CA 94720

C. Removal of Questionable Market Barriers

The Gregg-Schumer compromise bill addresses the issue of triggering 180-day exclusivity — the critical incentive for generic companies to challenge patents that prevent generic competition. Under current law, the 180-exclusivity is triggered either by a district court decision or the first commercial marketing of the generic product, which has significantly diminished this incentive. The district court decision trigger ignores the fact that the brand company can appeal the district court decision. The generic company, faces considerable risk if they launch their generic product during this appeal. If they do not launch the generic, the 180-day exclusivity period can evaporate while the appeals process is being completed. The generic company must decide whether to either forego the exclusivity period or market its generic version during the appeal and risk substantial financial penalties if the district court victory is overturned on appeal.

However, if the generic patent challenger and the brand company reach a settlement of the patent challenge suit and agree that the generic will not to go to market, there is never a trigger event for the 180-days of exclusivity. As a result, other generic products are precluded from coming to the marketplace, until the patents on the brand product expire.

S. 1225 restores this incentive by amending current law to the appellate court decision as the

triggering event for exclusivity. This will ensure that the incentive for a generic company to pursue a patent challenge is preserved.

The Gregg-Schumer proposal also includes a pro-consumer "use-or-lose provision," providing for the forfeiture of the exclusivity period upon certain circumstances. The Gregg-Schumer proposal also includes a "use-or-lose provision," providing for the forfeiture of the exclusivity period upon certain circumstances. These include: settlement of the patent challenge; failure to enter the market within 60 days of FDA approval; failure to receive FDA approval within 30-months; withdrawal of the generic product application; or a determination of anti-competitive activities by the Federal Trade Commission. Gregg-Schumer represents a significant compromise from S.812 which would have permitted a subsequent generic applicant to receive the exclusivity when such forfeiture occurred. Thus, the incentives for generic companies to challenge patents are preserved, and in fact strengthened, with the assurance of savings to consumers.

D. Mechanism to Remove/Correct Inappropriately Listed Patent Information

As the FTC Report noted, the FDA's failure to police the patent listing process combined with multiple 30-month stays presents "real world consequences" for consumers. The compromise bill would allow a generic applicant to challenge an inappropriate patent listing in a counterclaim to a patent infringement suit. There would be opportunity to correct or remove an inappropriately listed patent, but no monetary damages would be available.

E. Penalty for Failure to List Patents

In addition, S. 12225 would permit a court to consider a brand company's failure to file patent information as the basis for not awarding treble damages in a patent infringement case.

F. Codify the FDA's Bioequivalence Regulations

Finally, the Gregg-Schumer bill would codify the FDA's bioequivalence regulations to allow for the approval of generics in additional therapeutic classes. Currently, bioequivalence is demonstrated through clinical studies comparing the generic and brand drugs in the blood stream of clinical subjects. Brand companies have challenged FDA's statutory authority to determine the "bioequivalence" of drugs that are not intended to be absorbed into the bloodstream, such as topical creams, inhaled drugs, and eye or ear drops.

The Gregg-Schumer proposal would permit FDA to use scientifically valid alternative methods to determine the "bioequivalence" of generic and brand drugs when the drug's active ingredient cannot be measured in the blood. These alternative methods must ensure that the drug product is as safe and effective as the listed drug referred to in the application. This is a clarification of FDA's current regulations and policies.

IV. The President's Rule Complements S. 1225

GPhA and its members wholly endorse the President's message that measures must be taken to ensure timely access to affordable pharmaceuticals. GPhA applauds the President, and FDA for recognizing the importance of fostering pharmaceutical drug competition, and for taking measures to address anticompetitive conduct that has permeated the Hatch-Waxman system in recent years to the detriment of American consumers and health care providers.

GPhA believes that the White House rule providing patent listing clarification and requiring enhanced brand patent certifications is an important step toward improving consumer access to affordable generic drugs and complements the legislation. Yet, more measures outside of FDA's authority are necessary to ensure timely access. While making some strides toward reform, FDA's rule does not prevent brand companies from using loopholes to block generic competition, nor does it give generic companies the ability to obtain timely resolution of legitimate patent disputes. The rule could also weaken the 180-day generic exclusivity provision, which is an essential part of Hatch-Waxman.

Truly effective Hatch-Waxman reform requires a comprehensive approach, in which no single component of the system is viewed in isolation. Much like a complex mathematical equation, Hatch-Waxman reform must be assessed and undertaken as a whole to determine whether the entire system will yield the desired outcome of timely access to affordable medicine. Not only must any reforms prevent gaming of the Hatch-Waxman system; it must also ensure early resolution of legitimate patent disputes between generic and brand companies, so that these disputes are resolved and generic drugs may go to market as quickly as possible. The twin goals of preventing gaming of the Hatch-Waxman system and ensuring timely resolution of brand-generic patent disputes are completely reconcilable. And both goals must be achieved concurrently if the Hatch-Waxman balance is to be fully restored and only Congress can effectuate the necessary changes.

V. Conclusion

As the President explained in remarks made June 12, 2003, "[t]he [current] system a lot of times doesn't work because the original inventor of the drug uses delaying tactics to avoid competition. They delay the process of patent expiration so that consumers don't have additional choices of generic drugs."

GPhA strongly believes that the Administration's complementary initiatives, coupled with substantial measures in the compromise legislation, will ensure that American health care becomes more affordable. We urge the 108th Congress to enact the Gregg-Schumer legislation to assure consumers of the substantial savings that result from the timely introduction of generic pharmaceuticals.

Thank you.

June 17, 2003

WRITTEN TESTIMONY OF BRUCE N. KUHLIK
SENIOR VICE PRESIDENT AND GENERAL COUNSEL
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

The Pharmaceutical Research and Manufacturers of America appreciates this opportunity to share with the committee its views on the Federal Trade Commission's July 2002 report, "Generic Drug Entry Prior to Patent Expiration." PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives.

As the title of its report suggests, the Federal Trade Commission (FTC) studied the entry of generic drugs onto the market prior to expiration of the innovator's patents. Based on the data it gathered, the FTC made two recommendations, discussed below, to address innovator and generic manufacturer behavior that may slow generic drug entry. As explained in the executive summary to its report, however, the FTC did not examine the effect of its recommendations on incentives to innovate in medicine.

Our patent laws and regulations provide a key incentive for continued innovation. Changes in these rules could have a significant impact on the breadth and speed of medical progress in the years ahead. Better treatments – and even cures – can come only from the pharmaceutical research industry, and can come only if patent incentives are maintained. Allowing generic drug manufacturers to copy discoveries too soon will mean that many discoveries will never be made. Before discussing the FTC's findings and recommendations, therefore, this testimony explains why it is vitally important – to

patients and our health care system – to maintain an environment that brings emerging treatments to patients.

The Relationship between Patents Laws and Continued Discovery of Medicines

In recent years, citing rising drug costs, the generic industry and its allies have argued that the Hatch-Waxman Act should be revisited and in particular that patent incentives should be weakened to allow generic copies to enter the market more quickly. We believe this argument is flawed for several reasons. First, continued innovation in medicine is vitally important to millions of Americans awaiting better treatments and cures. Second, innovation in medicine offers the true solution to the challenges of better health care quality and lower health care costs. And third, spending on prescription medicines remains a relatively small portion of total health care spending.

Recent advances in treatment of Alzheimer's disease show how pharmaceutical innovation – not generic copies – represents the solution for patients and our health care system. New medicines to treat Alzheimer's show promise not only in overcoming the terrible effects of this disease, but also in easing the growing burden it imposes on our health care system and the families of people with the disease. In one study, a new medicine for Alzheimer's reduced health care spending on the disease by one-third, despite a four-fold increase in drug spending.

Pharmaceutical research companies are playing a leading role in finding new treatments to help delay or prevent the progression of Alzheimer's disease. Currently, there are 24 new medicines in development in this area. These new medicines, along with the current arsenal of FDA-approved medicines, are grounds for hope that there may be better treatments and, one day, a cure for Alzheimer's disease.

Many similar examples exist for diseases and conditions from asthma to cancer, from diabetes to heart disease. Currently, research-based pharmaceutical and biotechnology companies have more than 1000 drugs in development – either in human clinical trials or at FDA awaiting approval. The medicines in development include more than 800 in development for older Americans, 395 in development for cancer, 194 for children, 176 for neurological disease, 123 for heart disease and stroke, and 83 for AIDS.

Medicines like those under development improve not only patients' lives, but also our health care system. Research demonstrates that substituting newer medicines for older medicines – while it increases spending on prescription drugs – decreases overall health care spending.[1] Additionally, because medicines can help control disease and improve health, higher spending on medicines often leads to lower overall health costs. For example, a study that reviewed asthma patients' records in the North Carolina Medicaid program for one year before and one year after the introduction of inhaled corticosteroid therapy found that for those patients using inhaled corticosteroid therapy, there was a 50 percent decrease in hospitalization rates and a 26 percent decrease in outpatient visits. The group not receiving the medicines had a 23 percent increase in hospitalization rates and a 36 percent increase in outpatient visits. According to a cost analysis, use of the inhaled corticosteroid therapy reduced total health care costs by 24 percent per asthma patient per month.[2]

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[1] Frank Lichtenberg, "Benefits and Costs of Newer Drugs: An Update," NBER Working Paper No. 28996 (Cambridge, MA: National Bureau of Economic Research, June 2002) <http://www.nber.org/papers/w8996> (23 July 2003).

[2] R. Balkrishnan, MS (Pharm), et. al., "Outcomes and Cost Benefits Associated With the Introduction of Inhaled Corticosteroid Therapy in a Medicaid Population of Asthmatic Patients," *Clinical Therapeutics*. 20 (1998): 3.

While pharmaceutical research companies have made great progress in medicine over the past several decades, spending on prescription medicines remains a relatively small portion of our total spending on health care. Spending on pharmaceuticals (including the cost of brand name ingredients, generic ingredients, repackagers, wholesalers, prescription benefit managers and pharmacies) still accounts for only 10 cents of each dollar spent on health care in the United States.[3]

Prescription medicines also remain a small component of managed care premiums. In 2002 HMOs spent an average of just $27.79 per member per month (PMPM) on outpatient prescription medicines, out of an average total premium of $212.71 PMPM. In addition, spending on prescription medicines accounted for just $3 of the $32 increase in average monthly premiums between 2001 and 2002, according to data analyzed by PhRMA from Milliman USA.[4]

The rate of growth in spending on prescription medicines has fallen for the past three years. The continuing growth in spending reflects the fact that innovative medicines are helping more patients than ever before lead better, longer, more active lives.

Standards of medical care have changed, and in particular we place increasing emphasis on the use of medicines to manage symptoms and to prevent serious and life-threatening diseases. For example, new clinical guidelines emphasize greater use of

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[3] Centers for Medicare and Medicaid Services, "The Nations Health Dollar: 2001," 8 January 2003 <http:/cms.hhs.gov/statistics/nhe/historical/chart.asp> {21 January 2003).

[4] Milliman USA, "HMO Premium Increases to Average 17% in 2003: Milliman USA Survey Confirms Fifth Straight Double-Digit Advance," press release, 3 October 2002 & Milliman USA, 2001 HMO Intercompany Rate Survey (Brookfield, WI: Milliman USA Inc., 2001) as cited in Pharmaceutical Research and Manufacturers of America, "The Best Value in Medicine Today: How Prescription Drugs Account for a Fraction of Health Cost Increases While Helping to Offset Other Health Costs" (Washington, DC: PhRMA, 2002)

prescription medicines to treat high cholesterol and schizophrenia. Recently released standards for the treatment of high blood pressure emphasize greater use of prescription medicines for a broader range of patients, and the use of multiple medicines to reach treatment goals.

Pharmaceutical research companies have also developed new medicines for diseases that once had no treatment and have made significant advances in the treatment of other diseases. For example, medicines exist today to treat conditions such as Alzheimer's and AIDS, conditions for which either no treatment existed or treatment was limited previously. Prior to 1995, only one category of medicines (aside from insulin) was available to patients with type 2 diabetes. Since 1995, a new generation of that category plus new types of insulin and five new classes of prescription drugs to treat diabetes have reached patients.

It also is important to consider changes in the process of pharmaceutical innovation that have occurred since 1984. Over that time, the process of discovering a new medicine and bringing it to patients in need has become harder, more uncertain, and more expensive than ever before. Pharmaceutical research companies invested over $32 billion in researching and developing new treatments last year, an all-time high.

The increasing risk and expense of discovering new cures further underscores the importance of maintaining patent incentives. Key changes in the process of innovation include:

- The cost of discovering and bringing to market a new medicine has risen to over $800 million, more than doubling since 1987;
- Competition between brand-name medicines within a treatment class has become much more intense before patents expire;

- A much larger share of top-selling medicines now face generic competition after patent expiration;
- Generic copies take market share much more quickly upon entering the market;
- An entire industry of large prescription drug purchasers representing millions of patients has emerged and negotiates lower prices with manufacturers.

The Hatch-Waxman Act

The Hatch Waxman Act of 1984 is the most significant law affecting the pharmaceutical industry in the past forty years, having resolved many years of controversy about the Food and Drug Administration's (FDA's) policies and procedures governing marketing approval for generic drugs. The statute made three key changes in the law. First, it abolished most patent rights of innovator companies through the "Bolar amendment." This provision – unique in patent law – allows generics to manufacture and use drugs prior to patent expiration without liability for infringement. Second, the statute extinguished the proprietary rights to safety and effectiveness data previously enjoyed by innovator companies in perpetuity. Congress substituted in their place very limited five-year and three-year protections. Third, the Hatch-Waxman Act eliminated the costly and time-consuming safety and effectiveness testing requirements for generic drugs and substituted small-scale inexpensive bioequivalence testing in their place.

The Success of Hatch-Waxman

By any measure, the Hatch-Waxman Act has been a success. Generic market share has soared. In 1984, generic manufacturers held less than a 20 percent share of the prescription drug market. Today, their share of the total market is nearly 50 percent, and

when a generic drug is approved, it obtains an 85 percent market share within ten short weeks.[5]

Prior to the Hatch-Waxman Act's passage, it took generic drug makers between 3 and 5 years after patent expiration to enter the market.[6] Now generic drugs often enter the market the day after patent expiration, and in more and more cases, even before patent expiration. (At the same time, however, 93 percent of generic applications are not approved on the first try, and 66 percent are not approved even on the second round.[7]) During the 1980s, only 2 percent of generic applications contained paragraph IV certifications. From 1998 to 2000, approximately 20 percent did.[8] (Because of the increasing length of the R&D process, the effective patent life for new medicines is approximately 11 to 12 years.[9] The effective patent term on medicines is significantly shorter than the 20-year patent term granted in the United States and shorter than the average effective patent life of other U.S. products that is 18.5 years.[10]) More than one-

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5 Michael Johnsen, "Getting poised for a steeper growth curve; special report; generic drugs; industry overview," Drug Store News (February 17, 2003).

6 Frank R. Lichtenberg, "Public Policy and Innovation in the Pharmaceutical Industry," Public Policy and Entrepreneurship Symposium (Syracuse, NY: Center for Policy Research, Syracuse University, 20-21 April 2001).

7 Mark B. McClellan, M.D., Ph.D., Commissioner, Food and Drug Administration, Remarks to the Generic Pharmaceutical Association, 29 January 2003. <http://www.fda.gov/oc/speeches/2002/gpha.html> (June 16, 2003).

8 Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002) ("FTC Report"), ii.

9 H. Grabowski and J. Vernon, "Longer Patents for Increased Generic Competition in the U.S.: The Waxman-Hatch Acts After One Decade," *Pharmacoeconomics* 10 (1996): suppl. 2, 110-123.

10 American Intellectual Property Law Association, testimony of Michael K. Kirk on H.R. 400 before the U.S. House of Representatives Subcommittee on Courts and Intellectual Property, 26 February 1997.

quarter of paragraph IV certifications do not result in a lawsuit by the brand manufacturer.[11]

Before 1984, generics were required to develop and submit to FDA a data package comparable to an innovator company application. Today, their drug development costs are well under 1 percent of those for an innovator product. The cost of an abbreviated new drug application for a generic drug has been estimated in the range of $1 to $2 million, as compared to the $800 million involved in bringing a new innovator drug to market.

The FTC Study

In October of 2000, the Federal Trade Commission announced that it intended to conduct a focused study of generic drug competition, and in particular, "whether brand-name and generic drug manufacturers have entered into agreements, or have used other strategies, to delay competition from generic versions of patent-protected drugs."[12] The FTC was interested in two provisions of the Hatch-Waxman Act: the 180-day exclusivity available to the first generic applicant to file an abbreviated new drug application (ANDA) containing a paragraph IV certification,[13] and the 30-month stay of generic drug approval that applies if an innovator company receives notice of a generic company's

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[11] FTC Report, at 13.

[12] FTC Press Release, FTC to Study Generic Drug Competition (October 11, 2000).

[13] When a generic drug manufacturer files an ANDA, it must include a statement regarding every unexpired patent covering the innovator medicine that is listed with FDA in a publication known as the Orange Book. These statements, known as "paragraph" certifications based on specific paragraphs in the Hatch-Waxman Act (I, II, III, and IV), are made on a patent-by-patent basis. In a paragraph IV certification the generic drug maker states its intention to enter the market before the patent in question expires, and that it believes that the patent is invalid or that its generic copy does not infringe the patent.

paragraph IV certification and files suit for patent infringement within 45 days of that notice.

To accomplish this study, the FTC subpoenaed documents and information from brand-name and generic drug manufacturers and examined every instance since 1992 in which a generic manufacturer sought to enter the market prior to expiration of the innovator's patents.

The FTC's findings confirmed the generic drug industry's success under the Hatch-Waxman Act. On the whole, FTC concluded, "beyond any doubt, Hatch-Waxman has increased generic drug entry. Generic drugs now comprise more than 47 percent of the prescriptions filled for pharmaceutical products – up from 19 percent in 1984, when Hatch-Waxman was enacted."[18]

The FTC found, first, that 30 months historically has approximated the time required for FDA review and approval of the paragraph IV ANDAs of generic applicants that were not sued, and for district and appellate court resolution of ANDA-related patent infringement litigation. Thus, the FTC concluded, "it does not appear that the 30-month stay provision, as applied once to each ANDA for patents listed in the Orange Book prior to the ANDA's filing date, has a significant potential to delay generic entry beyond the time already necessary for FDA approval of the generic's ANDA."[19]

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[18] FTC Report at i.

[19] FTC Report, at iv.

Second, the FTC found very few instances of so-called multiple 30-month stays. In these 8 instances, which involved 7 brand-name drugs, patents were issued by the PTO after a generic drug maker filed an application for FDA approval. In other words, the generic manufacturer filed its application for FDA approval before the patents on the innovator drug expired, the innovator sued to enforce its unexpired patents, and the lawsuit triggered a 30-month stay. While the original matter was being resolved by the courts, the PTO issued an additional new patent covering the innovator drug, the innovator listed the patent and triggered a paragraph IV certification, the innovator filed suit to enforce the new patent, and a second stay (in one case as short as four months) was triggered. Out of approximately 6,000 generic drugs approved since 1984, however, the FTC identified only 8 instances in which innovator companies had received multiple stays.

Finally, the FTC found that 14 of 20 settlements of ANDA-related patent infringement litigation "had the potential" to delay the start of the first generic applicant's 180-day exclusivity. The Commission challenged two settlements involving three drugs, alleging that the settlements blocked subsequent generic entry and therefore had the potential to be anti-competitive. The FTC notes in its report that no further settlements requiring scrutiny have been entered into since April 1999. The FTC further noted that patent settlements may in fact be pro-competitive.

The FTC made two major recommendations and several minor recommendations. First, it recommended that FDA "permit only one automatic 30-month stay per drug product per ANDA to resolve infringement disputes over patents listed in the Orange Book prior to the filing date of the generic applicant's ANDA." Second, the FTC

recommended that Congress "pass legislation to require brand-name companies and first generic applicants to provide copies of certain agreements to the Federal Trade Commission." In particular, the FTC recommended notification requirements apply agreements that relate in any way to 180-day exclusivity, or that concern the manufacture, marketing, or sale of either the innovator product or the generic copy. The FTC's minor recommendations included that (a) FDA should clarify its listing requirements, and (b) generic applicants should be permitted to raise listability issues as a counterclaim in the context of patent infringement litigation initiated by the innovator.

Conclusion

The FTC report reaffirmed that the Hatch-Waxman Act is achieving its purpose of speeding the market entry of generic drugs. Changes to the Hatch-Waxman law that undermine incentives for innovation would do significant harm to patients, our health care system, and our society. While short-term savings to the pharmaceutical budget line might be achieved, new discoveries in medicine that can improve health care quality and curb spending would not be made.

Statement of Senator Patrick Leahy
"The FTC Study on Barriers to Entry in the Pharmaceutical Marketplace"
Senate Judiciary Committee
June 17, 2003

In April, Senator Grassley and I re-introduced the Drug Competition Act of 2001 (S. 946), joined by Senators Cantwell, Durbin, Feingold, Kohl and Schumer. This bill passed the Senate by unanimous consent last November, and I hope that in this Congress it is actually enacted into law. Prescription drug prices are rapidly increasing, and are a source of considerable concern to many Americans, especially senior citizens and families. Generic drug prices can be as much as 80 percent lower than the comparable brand name version.

While the Drug Competition Act is small in terms of length, it is large in terms of impact. It will ensure that law enforcement agencies can take quick and decisive action against companies that are driven more by greed than by good sense. It gives the Federal Trade Commission and the Justice Department access to information about secret deals between drug companies that keep generic drugs off the market. This is a practice that hurts American families, particularly senior citizens, by denying them access to low-cost generic drugs, and further inflating medical costs.

I am very happy to see Chairman Muris before the Committee today, for it was the Federal Trade Commission that played such an important role in exposing the issue of drug companies paying their generic competitors – and potential competitors – not to enter the marketplace. While the FTC has sued pharmaceutical companies that have made such secret and anticompetitive deals, as the then-Director of the Bureau of Competition Molly Boast testified before the Judiciary Committee in May 2001, the antitrust enforcement agencies are only finding out about such deals by luck, or by accident.

In fact, last fall the FTC released its long-awaited report on the entry of generic drugs into the pharmaceutical marketplace – the report that we are discussing here this morning. The FTC had two recommendations to improve the current situation and to close the loopholes in the law that allow drug manufacturers to manipulate the timing of generics' introduction to the market. One of those recommendations was simply to enact our bill, as the most effective solution to the problem of "sweetheart" deals between brand name and generic drug manufacturers that keep generic drugs off the market, thus depriving consumers of the benefits of quality drugs at lower prices. In short, this bill enjoys the unqualified endorsement of the current FTC, which follows on the support by the Clinton Administration's FTC during the initial stages of our formulation of this bill. We can all have every confidence in the common sense approach that our bill takes to ensuring that our law enforcement agencies have the information they need to take quick action, if necessary, to protect consumers from drug companies that abuse the law.

Under current law, the first generic manufacturer that gets permission to sell a generic drug before the patent on the brand-name drug expires, enjoys protection from competition for 180 days – a headstart on other generic companies. That was a good idea – but the unfortunate loophole exploited by a few is that secret deals can be made that allow the manufacturer of the generic drug to claim the 180-day grace period – to block other generic drugs from entering the market – while, at the same time, getting paid by the brand-name manufacturer not to sell the

generic drug.

Our legislation closes this loophole for those who want to cheat the public, but keeps the system the same for companies engaged in true competition. I think it is important for Congress not to overreact and throw out the good with the bad. Most generic companies want to take advantage of this 180-day provision and deliver quality generic drugs at much lower costs for consumers. We should not eliminate the incentive for them. Instead, we should let the FTC and Justice look at every deal that could lead to abuse, so that only the deals that are consistent with the intent of that law will be allowed to stand. The Drug Competition Act accomplishes precisely that goal, and helps ensure effective and timely access to generic pharmaceuticals that can lower the cost of prescription drugs for seniors, for families, and for all of us.

The second recommendation made in the FTC report is also of vital interest this morning, particularly given the FDA's new generic drug rule. The FTC suggests a modification of Hatch-Waxman to allow brand name drug companies to receive only one 30-month stay of FDA approval per new generic drug product to resolve patent infringement disputes. Allowing only one 30-month stay will dissuade brand name companies from filing frivolous patents with the FDA. Under current law, there is an incentive to obtain as many patents as possible for a drug, as these companies could use multiple patents to receive multiple stays of FDA approval, preventing cheaper generic drugs from reaching our local pharmacies. This issue has been dealt with extensively in the HELP Committee, and I will be a co-sponsor of the Gregg-Schumer-McCain-Kennedy bill which would limit the number of stays prescription drugs can receive.

I look forward to hearing from all of the panelists about the state of the prescription drug market and will be interested in hearing their suggestions for improving our drug patent laws. Overall, the Hatch-Waxman Act has done a superb job in speeding generic drugs to the market while protecting the patent rights of the brand name companies. Working in a bipartisan manner, we have the potential to save consumers billions in prescription drug costs by closing the few loopholes that have been discovered since the bill's passage eighteen years ago. I look forward to hearing what our witnesses have to say this morning, and I thank Senator Hatch for convening a hearing on an issue that has such an impact on the physical health and fiscal well-being of all our citizens.

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Consumer Federation of America

TESTIMONY OF

SENATOR HOWARD M. METZENBAUM (RET.)
CHAIRMAN

BEFORE THE

SENATE JUDICIARY COMMITTEE

REGARDING

LEGISLATIVE AND REGULATORY REPSPONSES TO THE FTC STUDY ON BARRIERS TO ENTRY IN THE PHARMACEUTICAL MARKETPLACE

JUNE 17, 2003

Good morning, Mr. Chairman, Senator Leahy and members of the Committee. My name is Howard M. Metzenbaum and I now serve as Chairman of the Consumer Federation of America (CFA).[1] This testimony is also endorsed by Consumers Union,[2] the publisher of Consumer Reports magazine. I appreciate your invitation to offer my comments regarding legislative and regulatory responses to the authoritative Federal Trade Commission (FTC) report on generic drugs issued last July. The FTC report detailed at length the many specious tactics used by drug companies to stall or thwart public access to less expensive generic drugs.

It is outrageous that the same companies that charge Americans the highest drug prices in the industrialized world would use secret payoffs, flimsy legal maneuvers and back room deals to eliminate generic competition, line their pockets and harm consumers. Every time a drug company blocks a safe, generic drug from getting into the hands of the American people, they are placing a tax on the uninsured, the poor, the sick and the elderly.

These outrageous attempts to keep drug prices high are particularly disgraceful, Mr. Chairman, because they undermine the effectiveness of one of your major achievements: the Drug Price Competition and Patent Restoration Act of 1984, also known has the Hatch-Waxman Act. You and Congressman Waxman provided great and wise leadership in drafting a law that represents a careful balancing act. It increased access to affordable, generic drugs, while insuring that drug manufacturers have adequate patent protection to justify substantial investment in research and development.

In other words, the Act promotes innovation and affordability. And it has helped bring down drug prices. The Congressional Budget Office estimated in 1998 that buyers saved roughly $8 to $10 billion in 1994 alone in pharmacy purchases, by substituting generic for brand-name drugs. At the same time, the wider availability of generic drugs certainly has not affected the profitability of drug manufacturers. According to researchers at Boston University, the pharmaceutical industry has been the most profitable sector of the economy for the last thirty years.

However, in recent years, as a number of top-selling "blockbuster" drugs were due to come off patent, brand drug manufacturers have used their political muscle and legal resources in a series of increasingly desperate attempts to block generic drugs from coming to market. For example, to protect the lucrative legal monopoly on its best-selling antihistamine Claritin, drug manufacturer Schering Plough made three separate attempts in the late 1990s to sneak through riders to appropriations bills that would have extended Claritin's patent. When that failed, they attempted to pass the infamous Claritin bill, which would have made it virtually impossible for the U.S. Food and Drug Administration (FDA) and the U.S. Patent and Trademark Office to stop a patent extension.

When these crass legislative efforts failed, the drug industry turned to their platoon of legal talent for help. They filed late patent claims just before a drug was to come off patent, sometimes on insignificant factors that had nothing to do with the therapeutic equivalence of a generic drug, such as the color or shape of a pill. They filed numerous "nuisance" lawsuits on the same drugs for violations of those late patents, triggering Hatch-Waxman's 30-month stay on the approval of the generic drug. They made secret payments to some generic companies to keep the generic alternative off the market.

All of these abuses were detailed in the FTC Report, "Generic Drug Entry Prior to Patent Expiration." I would like to provide you with the consumer perspective on the two major responses to this fine report: the recent bipartisan compromise reached on Senate legislation and a FDA rule promoted by the President that was finalized last week. These proposals overlap to some degree. In general, the bipartisan Senate compromise is much better for consumers because it deals more effectively with the range of abuses of the law that have occurred.

The Greater Access to Affordable Pharmaceuticals Act (GAAP)

Last year, the Senate passed GAAP by a wide, bipartisan margin, but the House of Representatives did not act on the bill. This year, Senators Kennedy, Gregg, McCain and Schumer have reached a bipartisan compromise on GAAP (S. 1225) that is expected to pass the Senate soon as part of Medicare prescription drug legislation. This bill has several strengths:

- **It would limit the ability of brand name drug manufacturers to prevent generic competition by triggering multiple 30-month stays on the same drugs. The bill would generally allow only one stay per drug to be granted.** The Hatch-Waxman Act sought to assure brand name drug companies that their patented products would not be infringed upon by generic drug makers who "jumped the gun" and introduced a competing product before the drug patent had expired. The law requires the FDA to stay approval of any generic drug for 30 months if the brand name company sues the generic drug maker for patent infringement. As the FTC report documents, brand name companies have improperly claimed additional patents for their products and then brought patent lawsuits to trigger 30 additional months of competition-free sales. The bill would generally allow only one stay per drug, as long as the patents are listed by the time a generic company files an Abbreviated New Drug Application (ANDA.) However, it is important to note that the restriction on multiple stays will apply to fewer patents at a later point under this compromise, than under last year's GAAP legislation (S. 812). Last year's bill only allowed a stay for patents that were already listed by a brand company at the time a new drug was approved by the FDA. The more permissive provision in S. 1225 will give brand companies a greater opportunity to manipulate the process by filing a later patent and then seeking a 30-month stay for patent infringement.

- **Generic companies would have the right to assure that their drugs are not in violation of any patent before going to market.** Under the bill, if a brand company does not bring a suit within 45 days of being notified of a generic firm's challenge to a patent, the generic "applicant" could go to court to see a declaratory judgment that no patents are being violated. Currently, the only way for a generic manufacturer to challenge an improper patent listed in the FDA's "Orange Book" is to certify that the patent is invalid or that the generic product does not infringe on the patent in question (paragraph IV certification). This action predictably leads to an infringement suit by the brand manufacturer against the generic, which automatically triggers a 30-month stay. Not only is the generic party to the suit prohibited from entering the market but the FDA is barred from approving market entry to any other generic within the same class. Strangely enough, the law enables a brand company to delay generic competition by simply not filing a patent infringement lawsuit.

By not acting, the brand company is holding out the threat of an infringement lawsuit in the future. In such a situation, most generic companies are unwilling to bring their drug to market, because they face the possibility of treble damages for patent infringement. The bill would provide a method for generic drug applicants to challenge improper Orange Book listings, resolving all outstanding legal issues with finality, without invoking a 30-month stay and stalling generic market entry.

- **It would help prevent anti-competitive contracts between brand name and generic drug companies, in which generic firms are paid by the brand-name drug company not to compete.** These "sweetheart" agreements violate the intent behind Hatch-Waxman, raise antitrust concerns and cost consumers millions of dollars a day. Such payoffs occur because Hatch-Waxman grants the first generic drug company to challenge the validity of a patent six months of "exclusivity" as the only company allowed to sell the generic version. The FTC has settled several cases in which a brand name drug manufacturer has paid a generic competitor not to market the generic alternative for the 180-day exclusivity period, allowing the brand drug to maintain its monopoly.[3] S. 1225 would require the first generic applicant to "use it or lose it." If the generic applicant fails to go to market within 60 days of final FDA approval or an appellate court decision, or fails to meet one of several other similar requirements, the company loses its six-month marketing monopoly.

- **It would take some moderate steps to reduce nuisance patent lawsuits.** Brand drug companies are required to list all patents that cover a specific drug with FDA in the Orange Book. Brand manufacturers have devised a way to keep their drug products from ever coming facing competition by filing new patents with the FDA at staggered intervals, so as one patent covering the drug product expires, it will still have patent protection.[4] The bipartisan compromise legislation would allow generic companies to challenge inappropriate patent listings, but only if they are sued first for patent infringement. It would also permit courts to consider a brand company's failure to file patent information as a basis for not awarding treble damages, which generic companies could face if found liable for a patent violation. It remains to be seen how effective these provisions will be in preventing obstructive litigation by brand companies. Both provisions are weaker than similar provisions in last year's GAAP legislation,[5] and may not provide as much of a disincentive against new frivolous patent listings with the FDA on the eve of drugs coming "off-patent."[6]

- **It would make it easier to bring several classes of generic drugs to the market.** Under the Hatch-Waxman Act, generics must prove they are "bioequivalent" to the brand name drug. Under current law, bioequivalence is determined by the absorption of a drug in a patient's blood stream, which is difficult to measure for many types of medications, such as topical ointments and inhaled medicines. While the bill would not change the FDA's current bioequivalence regulations, it clarifies existing FDA authority to amend those regulations.

The FDA's Final Generic Drug Rule

This final rule, first proposed by the President and the FDA in December, will complement the Senate bill in some ways. Overall, however, the final rule is unlikely to significantly reduce the anticompetitive tactics that I have cited today.[7] Even worse, by requiring the listing of new

categories of patents, like some product-by-process patents and some polymorph patents, it may actually encourage further abuse by brand drug companies of the patent listing process.

The rule does attempt to limit brand companies to one 30-month stay per drug if they believe a generic company has infringed on a legal patent. However, this restriction is much weaker than that in both the Senate compromise bill and last year's GAAP legislation. By allowing brand companies to seek a stay on all patents listed up until the generic drug enters the market, the FDA will allow brand companies to continue to game the system. Brand name companies will be able to list a late patent (with certain new restrictions) and then file a last-minute patent infringement lawsuit, improperly delaying consumer access to a generic drug that is about to go to market. By comparison, both the Senate compromise legislation and last years' GAAP bill would have allowed a 30-month stay only if the patent was listed much earlier in the process.

The rule's requirement that brand drug companies provide more information about the patents they are listing could help decrease the number of improper patent listings. However, while the initial rule required brand companies to submit a justification for the listing of all patents, the final rule only requires this justification for method-of-use patents. Moreover, the FDA failed to take the most significant step to minimize improper listings, which is to develop a procedure to review the adequacy of listings in the "Orange Book." In fact, the preamble of the final rule explicitly refuses to develop a "de-listing" procedure.

The FDA rule also takes a wrong turn by actually requiring certain additional patents to be listed in the Orange Book. Although this provision of the final rule is not as broad as the initial rule, it will still require new listings for some polymorph patents and some product-by-process patents. Moreover, although the final rule prohibits patents on metabolites, it does allow patents for "a method of using a drug to administer a metabolite," which could be abused. In its report, the FTC specifically highlighted the similarity of product-by-process patents to process patents, which cannot be listed in the Orange Book.[8] In fact, the FTC stated that product-by-process patents may be virtually indistinguishable from process patents. The FTC also raised serious questions about the listing of polymorph patents.[9] The FDA should not expand the scope of patents that are allowed to be listed to include these two patents. They do not fall within the three currently acceptable types of patents -- drug substance, drug product and method of use. There is a good chance that such an expansion would be abused by brand manufacturers and prove harmful to consumers' interests.

Conclusion

The pharmaceutical industry has repeatedly used improper delaying tactics to thwart access to generic drugs. This is not only a threat to the pocketbook of many Americans, but to their health. When faced with high drug costs, many people will go without needed medications or reduce the consumption of these drugs below the prescribed level. Senator Hatch and Senator Leahy, I urge you and members of the committee to support the bipartisan compromise legislation that will soon reach the Floor. Although the bill is not as strong as earlier legislation passed by the Senate, I applaud the efforts of Senators, Kennedy, Schumer, McCain and Gregg to find a compromise that will decrease drug costs and increase the flow of generic drugs to Americans in need.

Thank you for the opportunity to provide my comments.

[1] CFA is a non-profit association of some 300 pro-consumer organizations. CFA was founded in 1968 to advance the consumer interest through advocacy and education.

[2] Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of Consumer Reports, its other publications and from noncommercial contributions, grants and fees. Consumers Union's publications carry no advertising and receive no commercial support.

[3] American Health Lawyers Association, *Today in Health Law, FTC Settles Complaint Alleging Drug Company Blocked Generic Competition* (Executive Briefing Wednesday, April 24, 2002 - Volume 7, Number 79).

[4] See Pfizer's "Orange Book' listings for Neurontin (generic name gabapentin). Although Pfizer's patent for the active ingredient gabapentin expired in 1998, the company still has six patents filed with the FDA in the Orange Book protecting Pfizer's market monopoly on Neurontin. A generic is not on the market and Pfizer's last patent covering Neurontin is set to expire October 25, 2017.

[5] S. 812, as passed by the Senate in 2002, required brand companies to declare that they had provided complete and accurate information on all patents. It also provided generic companies that had filed an ANDA application with an affirmative private right of action to correct improper patent listing, not just as a right to file a counterclaim if sued. It also barred patent infringement suits for brand companies that did not list the applicable patent within 30 days of being approved.

[6] See In re Buspirone Patent Litigation, 185 F.Supp.2d 340 (S.D.N.Y. 2002). Bristol-Meyers Squibb submitted a new patent to the FDA covering BuSpar the day before drug was scheduled to go "off-patent." Generic equivalents, which were scheduled to be available on the market the day BuSpar's patent expired, were delayed for months.

[7] The Consumer Federation of America and Consumers Union submitted comments to the FDA on December 23, 2002 that supported the intent of the initial FDA proposal, but detailed several serious flaws in the proposal.

[8] "Generic Drug Entry Prior to Patent Expiration: An FTC Study," Federal Trade Commission, July 2003, pg. A-43.

[9] FTC Report at A-41.

Judiciary Committee Hearing
June 17, 2003
Statement of Senator Charles E. Schumer

Mr. Chairman, I want to thank you for holding this hearing and for your long-time commitment to the critical issue of ensuring pharmaceutical competition. I would also like to thank the Chairman and Ranking Member Leahy for their work on the Drug Competition Act which the Senate passed last year and for their ongoing commitment to keeping at the forefront the issue of anti-competitive behavior in the pharmaceutical marketplace.

And of course, I would like to thank Senator Gregg for his leadership in approaching me and bringing together Senators McCain and Kennedy, with whom I've worked on this issue for the past few years, to craft a strong, bi-partisan bill which is poised to roll through the Senate and which has a real chance of making it through the House as well.

The bill – which passed unanimously out of committee last week – achieves the goals of the original Schumer-McCain bill of closing the loopholes in the law (which I'm sure we'll hear more about from our witnesses here today) but it does so by modifying certain provisions to address the concerns that kept its critics from supporting it last year.

Before I get into a discussion of the bill, though, I'd just like to talk about the issue, and about how far we've come in bringing these abuses to light over the past few years.

Two years ago, Chairman Hatch called a hearing on this very same issue. At that time, we heard from the FDA, the FTC, and witnesses representing consumers and States who all shared their concerns about ways in which pharmaceutical companies were taking advantage of one of the most pro-consumer laws passed in the decades – the Hatch-Waxman Act.

That compromise was carefully crafted by Chairman Hatch and Congressman Waxman to strike a balance and help save consumers billions of dollars while rewarding brand name companies for their innovations. And for years, the law worked to do just that. But as the profits and stakes have become higher, drug industry lawyers have picked the Hatch-Waxman law clean. Companies are aggressively pursuing extended monopolies through collusive deals with generic manufacturers and by filing weak or invalid patents with the FDA.

Congress began to look at these abuses two years ago with Chairman Hatch's hearing.

What has happened since then?

(2)

First, the evidence has mounted.

In three additional hearings last year – in the Senate Commerce and HELP Committees, and in the House Energy and Commerce Committee – Congress heard how double-digit growth in drug costs and anticompetitive activity in the pharmaceutical industry has thrown corporations, State Medicaid programs, insurers, and consumers into a tailspin, as they struggle to pay for drugs and provide meaningful coverage.

The FTC released its report which documented abuse of several key loopholes in the law which are creating barriers to generic entry. Most significantly, the report identified eight blockbuster drugs, representing billions of dollars in sales, for which the brand companies listed patents late in the process and triggered successive 30-month stays of generic competition.

The big pharmaceutical companies have argued before Congress that these patents and the delays have been legitimate. Well, we've heard from the courts on 5 of these products. And so far – in every single instance – the courts have decided that these patents have been *invalid* or *not infringed* by the generic challenger. That doesn't sound too legitimate to me.

Let me just illustrate with an example.

(3)

The example is Paxil, a $2.1 billion drug used to treat obsessive-compulsive disorder, which has been in litigation since 1998. After the lawsuit began and the first 30-month stay was triggered, the brand company Glaxo SmithKline listed *nine* additional patents on the drug, which ended up triggering five additional 30-month stays.

Well, over the past year, there have been court decisions on 4 of those patents. The patent which began this litigation was found to be not infringed by the generic and the other three were found to be flat-out invalid. But the 30-month stays are *still* preventing generic competition. So far, these delays have cost consumers at least *$3 billion.*

Another thing that's happened since Chairman Hatch's hearing two years ago is that the FTC has shined light on the problem in it's study on barriers to generic entry in the marketplace, in addition to bringing multiple enforcement actions against both brand and generic companies for anticompetitive behavior. The State Attorneys General have also banded together to bring multiple suits against pharmaceutical companies and secured hundreds of millions of dollars in damages to compensate consumers and States for overpayments on drugs.

The Administration has also issued new regulations which clarify patent listing criteria.

Though all these actions are positive steps forward, none has the ability to put an end to the abuse. Congress must act to close the loopholes. The bill that Senators Gregg, McCain, Kennedy and I have introduced, which passed unanimously through committee last week closes the loopholes identified by the FTC and achieves the intent of the FDA rule without the ambiguity and uncertainty of a rule-making process.

The proposal we've put together makes it easier for less expensive, generic drugs to be sold in pharmacies and will significantly reduce overall drug spending in the US by billions of dollars.

That's not chump change – It's real savings and if there was ever a time that we needed those savings, it's now. America's economy is hurting and prescription drugs are a major source of the pain.

State Medicaid programs, businesses, employers, insurers are all struggling to pay for prescription drug coverage. Consumers of all ages are simply struggling to pay for prescription drugs.

This bill does something to reverse this situation. It's free market, pro-consumer, and it doesn't cost the government a penny.

The bill provides a critical complement to the work the FDA has done in clarifying its regulations on patent listings, but it goes much farther than the rule is capable of in ensuring that consumers will see real savings from closing these loopholes.

First, it gets rid of the potential for gaming of the 30-month stay by ensuring that they will not be triggered on the eve of generic competition. Second, it provides a mechanism to ensure that all patent disputes can be resolved before the generic goes to market – a concept at the very heart of Hatch-Waxman, which the FDA could not address through rulemaking.

Third, it ends the gaming of the 180-day exclusivity incentive granted to generics for challenging patents. Fourth, it includes a strong enforcement mechanism and a penalty provision which will give teeth to the FDA's new listing provisions.

So let me quickly detail how the Gregg-Schumer proposal paves the way for low cost drugs to come to market.

First, we give the name-brand companies a single 30 month stay that is triggered if the name-brand company challenges a generic application for infringing on one of its patents. If the name-brand company doesn't sue within 45 days of the generic application being submitted, we let the generic seek a declaratory judgement indicating that it does not violate the name-brand drug's patents.

Two, we allow generic companies to file counter-claims if a name-brand company sues them for violating a patent. For example, if a name-brand files a frivolous patent and sues a generic applicant for violating that patent in order to trigger the 30 month stay, the generic company can counter-sue the name-brand and argue that the patent should never have been listed in the Orange Book in the first place.

One of the concerns with the bill last year was that some thought it would create a flurry of lawsuits by the generic companies because it gave them a right to bring lawsuits to get frivious patents out of the Orange Book.

By giving the generic the ability to defend against patent challenges, but keeping it within the context of a lawsuit that has already been brought, we satisfy the goal and address the concern.

Three, to ensure that the first generic drug company who is able to come to market actually does come to market, we set up "forfeiture provisions" that would take away the 180 day exclusivity these companies get if they fail to come to market in a timely manner.

If one of the forfeiture provisions is invoked, the exclusivity would be forfeited and the marketplace would open up to any generic company ready to come to market.

This will put an end to the anti-competitive deals that brand and generic companies have entered into which have kept the lower priced drugs off the market and cost consumers hundreds of millions of dollars.

Four, we deal with the bioequivalence problem and clarify that the FDA has the authority to establish separate tests for determining the bioequivalence of drugs which are not absorbed into the bloodstream - as long as those tests are scientifically valid and meet rigorous standards.

Each part of this bill is key to closing the loopholes that exist. We have made some significant compromises since last year's proposal, and any attempts to weaken the current proposal will only do harm to consumers and to the effort to end the abuse.

The bottom line is that only Congress has the full authority to restore the balance envisioned in 1984 by Chairman Hatch and Congressman Waxman. Eighteen years ago, Congress passed one of the most pro-consumer pieces of legislation in decades. Since then, as the profits and stakes have gotten higher, lawyers for the industry have picked the law clean.

Gregg-Schumer-McCain-Kennedy is a strong bipartisan compromise that restores that balance. It does not cut innovators off at the knees and its not a gimme to the generic drug industry either. Congress must finish the job we started last year. I look forward to working with my colleagues to pass Gregg-Schumer in both chambers, have the President sign it into law, and put an immediate end to these abuses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

DANIEL E. TROY, CHIEF COUNSEL

U.S. FOOD AND DRUG ADMINISTRATION

BEFORE THE

COMMITTEE ON THE JUDICIARY

UNITED STATES SENATE

JUNE 17, 2003

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Daniel E. Troy, Chief Counsel for the United States Food and Drug Administration (FDA or the Agency). I am pleased to be with you today to discuss the Federal Trade Commission's July 2002 report entitled *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (FTC Report) and FDA's implementation of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments.

This testimony will discuss a number of issues that affect the timely introduction of generic drugs into the U.S. marketplace. It will focus in particular on whether certain "later-listed" patents or inappropriate patent submissions by the sponsors of innovator drug products have resulted in the delay of generic drug approvals. These matters were the subject of the FTC Report, which FDA has found to be invaluable in informing the Agency's response to the delays to generic drug approvals. As you may know, on June 12, 2003, FDA announced its final rule intended to speed access to and increase the availability of generic drugs by limiting the use of 30-month stays by brand-name drug sponsors and by clarifying the types of patents that must be submitted to FDA for listing in the Orange Book.

The Hatch-Waxman Amendments were intended to balance two important public policy goals. First, Congress wanted to ensure that brand-name (also known as innovator) drug manufacturers would have meaningful patent protection and a period of marketing

exclusivity to enable them to recoup their investments in the development of valuable new drugs. Second, Congress sought to ensure that, once the statutory patent protection and marketing exclusivity for these new drugs has expired, consumers would benefit from the rapid availability of lower priced generic versions of innovator drugs.

Since its enactment in 1984, Hatch-Waxman has governed the generic drug approval process. In general, the law has been working well. Since 1984, over 10,000 generic drugs have entered the market, and generics now account for close to 50 percent of prescriptions. Attention has recently focused on two key provisions of the law that allow for 180 days of marketing exclusivity to certain generic drug applicants, and for the 30-month stay on generic approvals. Both of these provisions are discussed in detail below.

FDA's objective is to enhance the ability of innovators, generic firms and the Agency to achieve the goals embodied in Hatch-Waxman. While the new rule will improve FDA's implementation of the law, this is only one part of a set of FDA initiatives that will reduce drug costs by encouraging innovation and speeding up the drug development and approval process, while maintaining FDA's high standards for safety and effectiveness. Our reforms in the generic approval process will generally shave months off the time to availability of generic drugs across the board. Similarly, new pathways for approving inhaled and topical drugs will potentially affect many products. This broad improvement in drug availability, both new drugs and generic drugs, will have a positive impact on all patients, not just those affected by imperfections in the operation of Hatch-Waxman.

STATUTORY PROVISIONS

The Hatch-Waxman Amendments amended the Federal Food, Drug, and Cosmetic (FD&C) Act and created a statutory generic drug approval process with section 505(j). Section 505(j) established the abbreviated new drug application (ANDA) approval process, which permits generic versions of previously approved innovator drugs to be approved without submitting a full new drug application (NDA). An ANDA refers to the clinical research and data in a previously approved NDA (the "listed drug") and relies on the Agency's finding of safety and effectiveness for the listed drug product.

The timing of an ANDA approval depends in part on patent protections for the innovator drug. Innovator drug applicants must include, in an NDA, information about patents relating to the drug product that is the subject of the NDA. FDA is required to publish the patent information submitted. The statute establishes a process that requires that ANDA applicants certify to the patents listed, provide notice to the NDA holder and patent owner, and, if patent infringement litigation is filed, imposes a 30-month stay on the approval of an ANDA. The Hatch-Waxman Amendments also created a period of market exclusivity for certain generic applicants.

"ORANGE BOOK" LISTINGS

Only certain types of patent information can be submitted to FDA. FDA publishes patent information on approved drug products in the Agency's publication Approved

Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book." The Orange Book is available on FDA's website and is updated every few weeks. The book is printed in hardcover yearly by the Government Printing Office, updated monthly and available to the public. It lists all approved drug products with their therapeutic equivalence codes in addition to the products' patent and exclusivity information (if such information exists).

Concerns have been expressed over FDA's role in the listing of patents in the "Orange Book," which can have an impact on generic drug approvals by delaying their approval and the initiation of 180-day exclusivity. Under the FD&C Act, pharmaceutical companies seeking to market innovator drugs must submit, as part of an NDA or supplement, information on any patent that: 1) claims the pending or approved drug or a method of using the approved drug, and 2) for which a claim of patent infringement could reasonably be asserted against an unauthorized party. Patents that may be submitted are drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method of use patents. Process (or manufacturing) patents may not be submitted to FDA.

When an NDA applicant submits a patent covering the formulation, composition, or method of using an approved drug, the applicant must also submit a signed declaration stating that the patent covers the formulation, composition, or use of the approved product. The required text of the declaration is described in FDA's regulations.

The process of patent certification, notice to the NDA holder and patent owner, a 45-day waiting period, possible patent infringement litigation and the statutory 30-month stay may result in a considerable delay in the approval of ANDAs when an innovator company submits a new patent listing to FDA. Therefore, ANDA applicants often closely scrutinize these listings. FDA's regulations provide that, in the event of a dispute as to the accuracy or relevance of patent information submitted to and subsequently listed by FDA, an ANDA applicant must provide written notification of the grounds for dispute to the Agency. FDA will then ask the NDA holder to confirm the correctness of the patent information and listing. Unless the patent information is withdrawn or amended by the NDA holder, FDA does not change the patent information in the "Orange Book."

If a patent is listed in the "Orange Book," an applicant seeking approval for an ANDA must submit a certification to the patent. Even an applicant whose ANDA is pending when additional patents are submitted for listing by the sponsor must certify to the new patents, unless the additional patents are submitted by the patent holder more than 30-days after issuance by the U.S. Patent and Trademark Office. Until the final rule effective date, pending generic drug applications are subject to multiple overlapping 30-month stays if new patents are listed for the innovator drug.

FDA does not undertake an independent review of the patents submitted by the NDA sponsor. The statute requires FDA to publish patent information upon approval of the NDA. This strongly suggests – and FDA has long held – that the Agency's role in the patent-listing process is intended to be ministerial. Issues of patent claim and

infringement are matters of patent law, and FDA lacks the authority, the resources, and the capability to assess whether a submitted patent claims an approved drug and whether a claim of patent infringement could reasonably be made against an unauthorized use of the patented drug. As such, FDA has implemented the statutory patent listing provisions by informing interested parties of what patent information is to be submitted, who must submit the information, and when and where to submit the information. Generic and innovator firms may resolve any disputes concerning patents in private litigation.[1]

Over the past few years, new patents have occasionally been submitted to FDA for listing in the "Orange Book" shortly before patents already listed in the "Orange Book" were scheduled to expire. These new patents have been submitted to FDA within the required 30-days of issuance by the Patent and Trademark Office. If the NDA sponsor complies with the requirements of the statute and regulations in submitting a patent for listing in the "Orange Book," the Agency may not reject a patent merely on the basis that, but for the filing of the patent, ANDAs would be eligible for final approval.

It has been suggested that FDA should review drug patents to determine if they should be listed in the "Orange Book" as protection for innovator drug products -- that is, FDA should assess whether a submitted patent properly claims the approved drug product and could support a claim of patent infringement. The Agency believes that, even if it had the authority and expertise (which it does not), such a review would not speed the availability of generic drugs. Rather, it would instead add a layer of complexity and

[1] *Mylan v. Thompson*, 268 F.3d 1323 (Fed Cir. 2001)—A generic's claim of improper listing "Is not a recognized defense to patent infringement."

delay, leading to litigation between FDA and the generic or innovator, in addition to any litigation between the generic and innovator.

Moreover, FDA review of patents would be unlikely to speed approval and marketing of generic drugs in a meaningful way even if FDA were to decide not to list a patent, the innovator company could obtain an injunction against approval or marketing of the generic drug until the patent listing question is resolved. In such a case, FDA's review of the patents would have done nothing to speed approval of generic drugs. Patent reviews would lead to substantial litigation that will impose a new and substantial burden on FDA's Office of the Chief Counsel and Department of Justice litigation resources. Finally, the Agency does not have the resources or expertise to review patents and, even with additional funding, is unlikely to be able to obtain the expert resources to do so.

DELAYS IN GENERIC DRUG APPROVALS – 30-MONTH STAYS

The FD&C Act requires that generic drug applicants include, in their ANDAs, a certification for each patent listed in the "Orange Book" for the innovator drug. Similar information is required for applicants filing 505(b)(2) applications under section 505(b)(2) of the FD&C Act. This certification must state one of the following:

(I) that the required patent information relating to such patent has not been filed;

(II) that such patent has expired;

(III) that the patent will expire on a particular date; or

(IV) that such patent is invalid or will not be infringed by the drug, for which approval is being sought.

A certification under paragraph I or II permits the ANDA to be approved immediately, if it is otherwise eligible. A certification under paragraph III indicates that the ANDA may be approved when the patent expires.

A paragraph IV certification, however, begins a process in which the question of whether the listed patent is valid or will be infringed by the proposed generic product may be answered by the courts before the expiration of the patent. The ANDA applicant who files a paragraph IV certification to a listed patent must notify the patent owner and the NDA holder for the listed drug that it has filed an ANDA containing a patent challenge. Until the effective date of FDA's final rule, all patents submitted and listed in the Orange Book, which are the subject of a paragraph IV certification, require notice to the NDA holder and patent owner. The notice must include a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the patent is not valid or will not be infringed.

The submission of an ANDA for a drug product claimed in a patent is an infringing act if the generic product is intended to be marketed before expiration of the patent. Accordingly, the ANDA applicant who submits an application containing a paragraph IV certification may be sued for patent infringement. If the NDA holder or patent owner files a patent infringement suit against the ANDA applicant within 45 days of the receipt

of notice, FDA may not give final approval to the ANDA for at least 30 months from the date of that notice.

This 30-month stay will delay approval of the generic drug product unless the court reaches a decision earlier in the patent infringement case or otherwise orders a longer or shorter period for the stay. A court may modify the length of a stay, under the FD&C Act, "if either party in the action failed to reasonably cooperate in expediting the action." (21 U.S.C. 335(j)(5)(iii))

Under FDA's traditional interpretation of the Hatch-Waxman Amendments, multiple 30-month stays have been possible. Submission of newly issued patents after an ANDA application has been filed with FDA has required the appropriate certification and notice to the NDA holder and patent owner with the possibility of a 30-month stay if patent infringement litigation resulted. As a result, there have been a number of instances in which delays in ANDA approval have exceeded 30-months.

A recent review of FDA's records indicates that of the 442 active ANDAs that contained paragraph IV certifications, only 17 have had multiple 30-month stays, representing 3.8 percent of all applications with patent challenges. However, we note that a significant number of these products have high dollar value annual sales, and we are aware of some instances where multiple stays have resulted in the delay of a generic drug approval for a number of years.

180-DAY EXCLUSIVITY

The Hatch-Waxman Amendments provide an incentive of 180 days of market exclusivity to the "first" generic applicant who challenges a listed patent by filing a paragraph IV certification and thereby runs the risk of having to defend a patent infringement suit. The statute provides that the first applicant to file a substantially complete ANDA containing a paragraph IV certification to a listed patent will be eligible for a 180-day period of exclusivity beginning either from the date it begins commercial marketing of the generic drug product, or from the date of a court decision finding the patent invalid, unenforceable or not infringed, whichever is first. These two events -- first commercial marketing and a court decision favorable to the generic -- are often called "triggering" events, because under the statute they can trigger the beginning of the 180-day exclusivity period.

In some circumstances, an applicant who obtains 180-day exclusivity may be the sole marketer of a generic competitor to the innovator product for 180 days. But 180-day exclusivity can begin to run -- with a court decision -- even before an applicant has received approval for its ANDA. In that case, some, or all of the 180-day period, could expire without the ANDA applicant marketing its generic drug. Conversely, if there is no court decision and the first applicant does not begin commercial marketing of the generic drug, there may be prolonged or indefinite delays in the beginning of the first applicant's 180-day exclusivity period. Approval of an ANDA has no affect on exclusivity, except if the sponsor begins to market the approved generic drug. Until an

eligible ANDA applicant's 180-day exclusivity period has expired, FDA cannot approve subsequently submitted ANDAs for the same drug. This is true even if the later ANDAs are otherwise ready for approval and the sponsors are willing to begin marketing immediately. Therefore, an ANDA applicant who is eligible for exclusivity can often delay all generic competition for the innovator product.

Only an ANDA containing a paragraph IV certification may be eligible for exclusivity. If an applicant changes from a paragraph IV certification to a paragraph III certification, for example, upon losing its patent infringement litigation, the ANDA will no longer be eligible for exclusivity.

The 180-day exclusivity provision has been the subject of considerable litigation and administrative review in recent years, as the courts, industry, and FDA have sought to interpret it in a way that is consistent both with the statutory text and with the legislative goals underlying the Hatch-Waxman Amendments. A series of Federal court decisions beginning with the 1998 Mova[2] case describe acceptable interpretations of the 180-day exclusivity provision, identify potential problems in implementing the statute, and establish certain principles to be used by the Agency in interpreting the statute. As described in a June 1998 guidance for industry, FDA currently is addressing on a case-by-case basis those 180-day exclusivity issues not addressed by existing regulations.

[2]*Mova Pharmaceutical Corp. v. Shalala,* 140 F.3d 1060, 1065 (D.C. Cir. 1998).

One of the most fundamental changes to the 180-day exclusivity program, resulting from the legal challenges to FDA's regulations, is the determination by the courts of the meaning of the phrase "court decision." The courts have determined that the "court decision" that can begin the running of the 180-day exclusivity period may be the decision of the district court, if it finds that the patent at issue is invalid, unenforceable, or will not be infringed by the generic drug product. FDA had previously interpreted the "court decision" that could begin the running of 180-day exclusivity (and the approval of the ANDA) as the final decision of a court from which no appeal can be or has been taken - generally a decision of the Federal Circuit. FDA's interpretation had meant that an ANDA applicant could wait until the appeals court had finally resolved the patent infringement or validity question before beginning the marketing of the generic drug.

FDA had taken this position so that the generic manufacturer would not have to run the risk of being subject to potential treble damages for marketing the drug, if the appeals court ruled in favor of the patent holder. The current interpretation means that if the 180-day exclusivity is triggered by a decision favorable to the ANDA applicant in the district court, the ANDA sponsor who begins to market during that exclusivity period now may run the risk of treble damages if the district court decision is reversed on appeal to the Federal Circuit. As a practical matter, it means that many generic applicants may choose not to market the generic and thus the 180-day exclusivity period could run during the pendency of an appeal.

FEDERAL TRADE COMMISSION STUDY

In response to reports of brand-name and generic drug companies engaging in anti-competitive behavior, the FTC conducted a study to determine if the 180-day exclusivity and the 30-month stay provisions of the Hatch-Waxman Amendments have been used strategically to delay consumer access to generic drugs. In July 2002, FTC published the findings of their study and provided two primary recommendations.

FTC recommended that only one automatic 30-month stay per drug product per ANDA be permitted to resolve infringement disputes over patents listed in the "Orange Book" prior to the filing date of the generic applicant's ANDA. FDA agrees with FTC's conclusion that recently, more ANDAs have been subject to 30-month stays, and more multiple 30-month stays, than in years past, and more patents on average are now being litigated per generic drug application than in the past.

FTC's second recommendation was to pass legislation to require brand-name companies and first generic applicants to provide copies of certain agreements to FTC. This is a response to FTC's finding that brand-name companies and first generic applicants have on occasion entered into agreements to delay generic competition. FDA has no objection to this recommendation.

FDA agrees with many of the conclusions of the FTC study and has found the factual information provided in the report to be extremely valuable in our own deliberations

regarding the generic drug approval process. One example of this is the compilation of information on the disposition of litigation surrounding patents filed after NDA approval. Finally, we note that FTC's report recognized that FDA does not have the capacity to review the appropriateness of patent listings.

FDA RULEMAKING

On June 12, 2003, President Bush, HHS Secretary Thompson and FDA Commissioner McClellan announced a new regulation to be effective in 60 days that will streamline the process for making safe, effective generic drugs available to consumers. This rule was first proposed on October 24, 2002, in response, in part, to the FTC recommendations and other changes the Agency identified as being useful in improving generic competition. The new rule will limit an innovator drug company to only one 30-month stay of a generic drug applicant's entry into the market for resolution of a patent challenge. The changes in the regulations will save consumers an estimated $35 billion over ten years by making generic alternatives to certain more costly brand-name drugs available more quickly, by avoiding time-consuming legal delays. The new regulations will be published as a final rule in the *Federal Register* on June 18, 2003. The rule will be effective on August 18, 2003.

The rule provides a full opportunity for only one 30-month stay per ANDA or 505(b)(2) application; prohibits the submission of patents claiming packaging, intermediates, or metabolites; requires the submission of certain patents claiming a different polymorphic

form of the active ingredient described in the NDA; adds a requirement that, for submission of polymorph patents, the NDA holder must have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA; makes changes to the patent information required to be submitted and provides declaration forms for submitting that information to FDA, both with the NDA and after NDA approval; and does not require claim-by-claim listing on the declaration form except for method-of-use patents claiming approved methods of use.

30-Month Stay Provisions

The final rule limits brand-name companies to only one 30-month stay. The rule accomplishes this by establishing when generic companies must provide notice of a paragraph IV patent challenge to a brand-name sponsor and the patent owner (which initiates the 30-month stay process). Notice of a paragraph IV certification must be provided with an initial paragraph IV certification and when a previous certification and notice did not result in a full opportunity for a single 30-month stay.

If an ANDA or 505(b)(2) application is amended to include a paragraph IV certification, notice must be provided to the NDA holder and patent owner only if the application did not already contain a paragraph IV certification or there was not a full opportunity for a 30-month stay. If an ANDA or 505(b)(2) applicant changes its paragraph IV certification before the 45-day period after notice to the NDA holder and patent owner has expired, and the NDA holder or patent owner has not initiated patent litigation, such paragraph IV certification and related notice are not considered to have satisfied the

requirement of providing one notice of a paragraph IV certification and a full opportunity for a 30-month stay.

Generic drug applicants will still have to file paragraph IV certifications to FDA, and the ability of brand-name firms to obtain patents and to challenge alleged infringement in court is undiminished. They will not, however, be able to forestall approval of a generic version of a drug by engaging in submitting later-issued patents or repeated patent filings. These later submissions will no longer result in multiple 30-month stays.

Requirements for Drug Patent Submissions

Under the final rule, drug manufacturers will not be allowed to submit patent information for listing in the Orange Book for drug packaging, drug metabolites, and intermediate forms of a drug. Permitted submissions include patent information on drug product (active ingredients), drug substance (formulation/composition), and approved uses of a drug.

In addition, patent submission declarations will be more detailed. There are mandatory forms that must be used to submit patent information to FDA. The forms include a series of questions with check-off boxes to be completed that provide details on the type of patent information submitted. The questions request information on whether the patent is one of the type permitted or not under the regulations, whether the patent is a product-by-process patent and the product claimed is novel, whether the method of use is

an approved method of use and the relevant indication included in the approved labeling, and other relevant information.

The declarations must be filed with the NDA, amendment, or supplement, and for patent information submitted after NDA approval. The check-off questions are designed so that FDA does not have to do anything more than quickly review the form to determine whether the patent information is eligible for listing. A signed attestation is required on the declaration form that requires that the submitter attest to the familiarity with the regulations and the information submitted. A warning is included that a willfully and knowingly false statement in the attestation can lead to criminal charges. These changes will significantly reduce opportunities to submit inappropriate patents for listing in order to delay approval of generic drugs and prevent fair competition

INITIATIVE ON IMPROVING ACCESS TO GENERIC DRUGS

Concurrent with FDA's June 12, 2003, announcement on publication of its final rule, President Bush announced an initiative on Improving Access to Generic Drugs, which includes the following components:

- A proposed increase of $13 million in Fiscal Year 2004 in FDA resources devoted to improving access to generic drugs.

The proposed addition in the President's fiscal year 2004 budget of an additional $13 million in spending for FDA's generic drug programs would be the largest annual infusion of resources into

the generic drug program ever, increasing the program's size by about one-third. FDA will be able to hire about 40 additional staff in generic drugs and expand the new chemistry review division in the Office of Generic Drugs. This expansion should help reduce the average review time by at least two months, increase the percentage of reviews that are completed within 180 days, approach the goal of reviewing 100 percent within 180 days and further reduce the time it takes FDA to review.

- New processes to reduce the time and cost of generic drug approvals.

Beginning in the next fiscal year, FDA will make significant changes in its processes for approving generic drugs. In particular, the FDA will implement early communications with generic drug manufacturers to discuss their applications. FDA will increase the number of guidances available for generic manufacturers regarding what is required to prepare and submit quality, complete applications. FDA will also institute regular meetings with generic trade associations to discuss the process for improving the quality of applications and to impart information on changes in policies and procedures. Studies of FDA processes for new drugs indicate that early communications and more explicit guidances can often improve drug applications and allow deficiencies to be corrected while an application is under review, rather than having to wait for additional review cycles to fix problems. This can significantly reduce the time it takes to approve a drug.

- Enhanced public education and scientific study of generic drugs.

FDA will expand its educational programs and partnerships involving generic drugs to help health care practitioners and consumers get accurate information about the availability of generic drugs for health care needs. FDA will also undertake additional scientific studies of certain types of generic drugs where adequate bioavailability methods have not been adequately developed, to make it easier to approve these generic drugs. FDA will also enhance the monitoring of the safety of generic drugs currently on the market.

These steps to improve access to generic drugs are expected to reduce the average time for most generic drug approvals by three months or more. Because this approach to increase availability will apply to all generic drugs, it can have a substantial impact on health care costs. In particular, faster access and a lower-cost approval process for the hundreds of generic drugs expected to come on the market would be expected to save consumers many billions. Improved consumer education and generic drug science is also intended to lead to additional savings from greater confidence and use of generic drugs.

OTHER SIGNIFICANT BARRIERS TO GENERIC DRUG AVAILABILITY

Although patent-related challenges have delayed approval of generic drugs in a number of high-profile cases, there are a number of other important barriers to generic competition. These barriers, which usually result from insufficient scientific knowledge

and standards, are likely to become even more significant as scientific advances in drug development lead to new forms of therapy.

Currently, some classes of drug products entirely lack generic versions because scientific methods for evaluating their bioequivalence are not available. Examples include the nasal and inhaled corticosteroids used for allergy and asthma treatment. Prospective manufacturers of inhaled or topical generic drugs face uncertainty and high development costs, and thus few such products have been developed. Other widely used drugs, such as conjugated estrogens (available since the 1940s), lack generic competition due to scientific uncertainty about the composition of the active ingredient (s). Disputes over composition and bioequivalence standards also have caused delays in approval of many generic drugs while innovator challenges to the standards are evaluated. Scientific research to support the development of additional standards in these areas would enable FDA to approve drugs in additional classes, and also to deal with scientific challenges to pending generic drug approvals more expeditiously.

Innovations in drug therapy are leading to new methods of drug delivery, including via liposomes, implantable systems, transcutaneous or transmucosal products, and inhalation methods. At the same time, due to innovations in chemistry, drugs with very complex molecular structures are possible. If generic copies of such innovative therapies are eventually to be made available, standards must be developed to accommodate these products within the Hatch-Waxman framework. This includes work on issues of

composition, formulation and bioequivalence. Scientific research in each of these areas is needed to support new standards.

Some of the FY 2004 budget increase for the generic drug program noted above will allow for additional bioequivalence research on inhalers, topical generics, and other dosage forms, so that in the future, new classes of generics can be made possible. This is a long-term research need that will take time and a lot of effort, but FDA is dedicated to opening up these new product areas.

RECENT SENATE ACTION ON GENERICS LEGISLATION

We are pleased to note that in addition to our actions designed to speed access to generic drugs, last week the Senate Committee on Health, Education, Labor and Pensions by unanimous consent ordered reported legislation on generic drug access. This agreement is an important step forward. We recognize and appreciate Chairman Gregg's leadership in achieving a bipartisan agreement with the other original sponsors of the bill. We are pleased that the proposed legislation includes key ideas embodied in FDA's regulation to improve access to generic drugs, and does not include certain other problematic provisions contained in legislation (S. 812) that passed the Senate last year. In this highly complex and technical area of law, we do have some concerns with the workability of the bill that we believe must be resolved for the legislation to achieve its intended effect, and we are working with the original sponsors and other Members to address the various technical and policy issues.

CONCLUSION

Greater access to generic drugs will reduce health care costs because the price of generic drugs is typically much lower than the brand-name drug. Reducing expensive lawsuits over drug patents and making the approval process more efficient will also help to lower national health care costs by reducing the cost of bringing safe and effective generic drugs to market. Thanks to the President's leadership, we are making real progress to build on his initiatives on speeding access to generic drugs by finalizing a generic drug rule that will save consumers $35 billion over 10 years by increasing access and availability to generic drugs.

FDA continues to implement the Hatch-Waxman Amendments exclusivity provisions in the best manner possible given the text and history of the legislation, and the numerous court challenges. In doing so, FDA has tried to maintain a balance between innovation in new drug development and expediting the approval of lower-cost generic drugs, as Congress sought to do in enacting this statute. We are confident that the President's initiative and the Agency's regulatory changes will go far towards achieving these goals, and improving health care outcomes as a result.

Thank you for the opportunity to discuss these important issues with you, and I will be happy to answer any questions you may have.